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As filed with the Securities and Exchange Commission on November 8, 2022.

Registration No. 333-267911

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

AMENDMENT NO. 2
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Acrivon Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**82-5125532**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

480 Arsenal Way, Suite 100
Watertown, Massachusetts 02472
(617) 207-8979
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 8, 2022
PRELIMINARY PROSPECTUS

5,900,000 Shares

Common Stock

We are offering 5,900,000 shares of our common stock. This is our initial public offering, and no public market currently exists for shares of our common stock. We expect the initial public offering price to be between $16.00 and $18.00 per share. Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "ACRV."

We are an "emerging growth company" and a "smaller reporting company" as defined under federal securities laws, and, as such, will be subject to reduced public company reporting requirements for this prospectus and future filings. See the section titled "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company." Investing in our common stock involves risks. See the section titled "Risk Factors" beginning on page 13.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	***Total***
Initial Public Offering Price	*$*	*$*
Underwriting Discounts and Commissions (1)	*$*	*$*
Proceeds, before expenses, to us	*$*	*$*

(1) We refer you to "Underwriting" for additional information regarding total underwriter compensation.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 885,000 shares of our common stock.

The underwriters expect to deliver the shares of common stock against payment in New York, New York on or about November , 2022.

MORGAN STANLEY *JEFFERIES* *COWEN* *PIPER SANDLER*

Prospectus dated November , 2022

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

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

OncoSignature is our trademark and is used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Through and including , 2022 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, 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.

PROSPECTUS SUMMARY

This summary highlights, and is qualified in its entirety by, information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes appearing elsewhere in this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our," "the company," "Acrivon" and "Acrivon Therapeutics" refer to Acrivon Therapeutics, Inc. and, where appropriate, our subsidiaries.

Overview

We are a clinical stage biopharmaceutical company developing precision oncology medicines that we match to patients whose tumors are predicted to be sensitive to each specific medicine by utilizing our proprietary proteomics-based patient responder identification platform. Recently approved targeted oncology treatments, such as kinase inhibitors, have transformed the cancer treatment landscape, and while the therapeutic benefit of these agents has provided significant benefit to patients, these targeted oncology treatments unfortunately only address the less than 10% of patients with cancers that harbor certain easily-identifiable genetic mutations. Our approach is designed to overcome the limitations of genomics-based patient selection methods. We do this by using our proprietary precision medicine platform, Acrivon Predictive Precision Proteomics, or AP3, to develop our pipeline of oncology drug candidates. Our AP3 platform enables the creation of drug-specific proprietary OncoSignature companion diagnostics that are used to identify the patients most likely to benefit from our drug candidates, which we refer to as patient responders. We are currently advancing our lead candidate, ACR-368, a selective small molecule inhibitor targeting CHK1 and CHK2 with sub single-digit nM and single-digit nM potency, respectively, in a potentially registrational Phase 2 trial across multiple tumor types, which our AP3 platform predicts will have a high proportion of patient responders based on OncoSignature-predicted sensitivity to ACR-368. Our ACR-368 OncoSignature test, which has not yet obtained regulatory approval, has been extensively evaluated in preclinical studies, including in two separate, blinded, prospectively-designed studies on pretreatment tumor biopsies collected from patients with ovarian cancer treated with ACR-368 in past Phase 2 clinical trials conducted by Eli Lilly and Company, or Lilly, and at the National Cancer Institute, or NCI, demonstrating robust enrichment of responders through our method.

The AP3 approach is proteomics-based and designed to enable identification and treatment of the patients whose tumors are sensitive to a specific drug or drug candidate based on direct protein measurement of critical tumor-driving mechanisms and independent of underlying genetic alterations. We believe our approach is applicable across stages of drug development and across therapeutic modalities. Accordingly, the AP3 method is not limited to the typically very small subset of cancers driven by single gene driver mutations or susceptible to a synthetic lethal approach. Rather, we believe our method is broadly applicable to the vast majority of cancers, in particular the majority of solid tumors, for which genetics-based approaches have proven insufficient to identify patient responders in many cases. In principle, we believe a much larger percentage of tumors can be addressed therapeutically using agents attuned to the specific biochemical signaling pathways found in these tumors, which our AP3 platform was purposefully designed to enable.

By applying our highly specific patient selection approach to drug development, we seek to both accelerate clinical development and significantly increase the probability of successful treatment outcomes for patients. Our pipeline includes the Phase 2 lead program, ACR-368, also known as prexasertib, a targeted oncology asset that targets CHK1 and CHK2, or CHK1/2. ACR-368 has been dosed in more than 400 patients at the recommended Phase 2 dose, or RP2D, with reported deep, durable responses, including complete responses, or CRs, in a proportion of patients with solid tumors in past single center and multi-center Phase 2 clinical trials in tumor indications with high unmet need. ACR-368 has also demonstrated a favorable safety and tolerability profile with

primarily reversible hematological toxicity and very limited non-hematological toxicity. We have received clearance from the U.S. Food and Drug Administration, or FDA, for an Investigational New Drug, or IND, application to advance ACR-368 in Phase 2 single arm clinical trials conducted under the FDA program known as the master protocol, which was developed to help expedite drug development in multiple tumor types for drugs with an established RP2D within the same overall trial structure. Initially, patients with platinum-resistant ovarian, endometrial, or bladder cancer will be treated in this trial. Patients will be stratified for treatment based on OncoSignature-predicted sensitivity to ACR-368 across multiple sites in the United States in this trial with registrational intent. Through the use of our OncoSignature test, we believe we can significantly increase the overall response rate, or ORR, observed in previous trials that were conducted without a prospective patient responder identification method.

We also plan to study ACR-368 in additional indications, such as human papilloma virus positive, or HPV^+, squamous cell carcinomas, including squamous cell cancer, or SCC, of head and neck, or SCCHN, anal, and cervical cancer, based on demonstrated clinical single agent activity in SCCHN and anal cancer and OncoSignature-based prediction of sensitivity to ACR-368 in a proportion of patients. In addition to ACR-368, we are also developing internally-discovered preclinical stage pipeline programs targeting critical nodes in the DNA Damage Response, or DDR, and cell cycle regulation pathways, including WEE1, a protein kinase, and PKMYT1, a closely related protein serine/threonine kinase.

Our AP3 Platform

Our AP3 platform is based on our proprietary approach developed to enable treatment of the patients who are most likely to respond to any particular drug candidate based on dependency in the tumor on the upregulated specific biochemical pathways that each drug modulates. Hence, our approach is tumor-agnostic: if the pathways the tumor depends on for its survival and growth, and that the drug candidate modulates, are upregulated, we predict that individual patient's tumor will be sensitive to the drug candidate. This applies regardless of the tumor origin and is independent of underlying genetic alterations. We are applying AP3 broadly to clinically active drug candidates as well as carefully selected preclinical lead series with a strong clinical rationale, and for which there is no obvious patient selection path through standard companion diagnostic approaches. We also intend to explore the use of AP3 with approved drugs to improve the ORR and outcomes for patients through our patient selection approach.

One of the key outputs of our AP3 platform are our proprietary, response-predictive clinical tests that we refer to as OncoSignature tests. These are drug-tailored, automated, quantitative proteomic tissue imaging tests applied to pretreatment tumor biopsies as a companion diagnostic, or CDx, to select and treat the patients predicted to benefit from the drug candidate. Our OncoSignature test, which has not yet obtained regulatory approval, is being developed with Akoya Biosciences, Inc., or Akoya, pursuant to a companion diagnostic agreement. Our OncoSignature tests encompass a signature of three classes of functionally-defined protein biomarkers assembled into a single signature assay. The quantitative levels for each of the three biomarkers are defined to determine whether a patient's individual tumor has upregulated the biochemical signaling mechanisms that the drug modulates and that the tumor depends on for growth and/or survival. For example, in the case of ACR-368, which is a selective CHK1/2 inhibitor, the three biomarkers we quantify with our ACR-368 OncoSignature assay measure the level of activated DNA repair downstream of the activated drug targets and whether the tumor likely depends on it. Our company name, Acrivon, is derived from Greek for "accurate." We chose it to embody how our OncoSignature tests are designed to accurately match our therapies with patients who will benefit.

The tumor-agnostic application of OncoSignature tests enables us to identify and focus on tumor types for which a high unmet need for a treatment exists and that are predicted to be highly sensitive to our drug candidates. We achieve this by deploying our OncoSignature screening of human cancer samples across various tumor types. Through this process, we can identify new tumor types predicted to be sensitive to a drug candidate

and even estimate the percentage of predicted responders before entering clinical trials. For example, we have identified endometrial cancer and bladder cancer as two highly sensitive cancer types for ACR-368, and therefore will include patients with these tumor types in our Phase 2 trials. Moreover, we have found through this approach that a proportion of patients with HPV+ cancers are predicted to be responsive to ACR-368 consistent with previously demonstrated clinical activity in a proportion of patients with SCCHN and anal cancer. Furthermore, we predicted that patients with squamous non-small cell lung cancer, or sqNSCLC, would not respond to ACR-368, consistent with an observed 0% ORR in patients with this tumor type in a past trial with ACR-368. Hence, through our OncoSignature screening approach, we can specifically avoid running clinical trials in cancer types predicted to have limited sensitivity to the drug candidate.

We are not only using our AP3 platform to generate drug-tailored, response-predictive clinical OncoSignature tests, but we also use our AP3 platform to provide unbiased, quantitative analyses of off-target effects on intracellular signaling using phosphoproteomic profiling, potentially enabling us to discover inhibitors that are both highly potent and highly selective.

We believe that by leveraging our AP3 platform and clinical OncoSignature tests, we will profoundly alter precision oncology drug development and the treatment landscape of patients suffering from cancer.

Our Pipeline

Our Lead Clinical Candidate ACR-368

ACR-368 is a selective small molecule inhibitor targeting CHK1/2. CHK1/2 are key regulators of the cell cycle and of DDR and inhibition of CHK1/2 has been demonstrated to have anti-tumor activity in multiple preclinical models as well as in clinical trials in humans. Several CHK1/2 inhibitors including ACR-368, also known as prexasertib, have been investigated in the clinic; however, none have been approved by the FDA. ACR-368 has shown deep, durable single agent clinical activity, including CRs and partial responses, PRs, in a proportion of patients with solid tumors with high unmet need for a treatment, such as platinum-resistant ovarian cancer, and SCCs, including SCCHN and anal cancer. More than 400 patients with these tumors have been treated with ACR-368 monotherapy at the RP2D in advanced single- and multi-center clinical trials conducted by Lilly, NCI, and at MD Anderson Cancer Center, or MDACC. The ORR in these trials without a predictive biomarker was 29% at the single center Phase 2 ovarian cancer trial at NCI in the intent to treat, or ITT,

population, and approximately 12% across the platinum-resistant ovarian cancer cohorts in the large Phase 2 multi-center international trial sponsored by Lilly. The median duration of response, or mDoR, at the RP2D across trials to date have ranged from almost six months to 12 months, and ACR-368 monotherapy demonstrated a generally favorable safety and tolerability profile with primarily reversible hematological toxicity and very limited non-hematological toxicity. Based on these two trials, encompassing over 200 patients with ovarian cancer, primarily platinum-resistant, we believe the unenriched background ORR in a larger patient population of platinum-resistant ovarian cancer is somewhere between 15% and 20%.

Using our AP3 platform, we have developed a predictive OncoSignature test for ACR-368, called ACR-368 OncoSignature, that we believe can predict patient response to ACR-368 monotherapy and therefore substantially improve the clinical ORR and, furthermore, that, we believe, has the potential to enable expedited drug development.

By applying our ACR-368 OncoSignature test for indication finding and expansion across human cancer types we have found that approximately 30% of samples from patients with ovarian cancer are ACR-368 OncoSignature-positive. Moreover, we observed that between 30% and 40% of patients with endometrial and bladder cancer are predicted highly sensitive to ACR-368. Patients with these two types of cancer were not previously treated in clinical trials. All three tumor types are therefore included in our upcoming Phase 2 clinical trial.

We have also used our AP3 platform to identify resistance mechanisms to ACR-368. Through phospho-proteomic profiling of human tumor cell lines that are either highly sensitive or highly resistant to ACR-368, we uncovered key resistance mechanisms and found that very low dose gemcitabine, or LDG, could be used to overcome resistance and further sensitize human tumor cells to ACR-368 through inducing increased DDR stress.

Based on these results, we are initiating a Phase 2 clinical trial where we intend to treat patients with all three tumor types: platinum-resistant ovarian, endometrial, and bladder cancer. ACR-368 OncoSignature-positive patients, which we believe will represent 30% to 40% of patients of each tumor type, will receive ACR-368 monotherapy in a single arm Phase 2b trial for each of the three tumor types. The ACR-368 OncoSignature-negative patients with these three tumor types will receive ACR-368 combined with LDG in a Phase 1b trial, followed by expansion into a Phase 2 trial with the combination in all three tumor types. As a result, all patients biopsied with these tumor types will have the opportunity to receive therapy. This Phase 2 clinical trial design and protocol has been cleared by the FDA and we have begun enrolling patients. Akoya will procure and manufacture the necessary supplies to perform the OncoSignature tests used in the Phase 2 clinical trial. Based on our communications with the FDA to date, we believe this trial, if successful, has the potential to be registrational for ACR-368 in each of the three tumor types. We believe that use of our ACR-368 OncoSignature test to select patients predicted to be sensitive to ACR-368 for treatment will significantly increase the ORR, which has the potential to lead to accelerated approval for multiple cancers while avoiding treatment of patients with tumors that are not likely to respond. However, we cannot guarantee that the FDA will permit us to utilize an expedited approval process or that our intended approach will be sufficient for regulatory approval. We are planning to file an IND application amendment to add three additional cancer types under the same trial protocol design at a later time, including head and neck cancer, anal cancer, and cervical cancer.

Our Preclinical Programs

We also have two preclinical drug programs designed to take advantage of our AP3 platform and the ability to predict tumor sensitivity based on custom OncoSignature tests. Both of these programs are structure-guided with rational medicinal chemistry efforts based on co-crystallography of lead series with their respective targets.

The first of these is directed at WEE1, a critical node in the DDR pathways. WEE1 inhibitors have demonstrated promising anti-tumor activity in early clinical trials conducted by competitors; however, the ORRs have been limited across key trials and we believe a patient selection method is required to achieve a sufficient

ORR for ultimate approval. The second, equally advanced preclinical program is directed at PKMYT1, a closely related protein serine/threonine kinase also serving critical functions in the cell cycle and DDR pathways. Based on mechanism of action and preclinical studies there is a rationale and data suggesting that inhibition of PKMYT1 will result in clinical activity. Currently one company has advanced a PKMYT1 inhibitor into phase 1 clinical trials. We believe the compound is in need of a patient selection method in the clinic and that genetics-based patient selection methods will be challenging.

Based on results from our AP3 platform, we believe that we can predict drug-sensitivity using our proteomics-based approach for patient responder identification with our OncoSignature tests. We anticipate advancing our WEE1 inhibitor and PKMYT1 inhibitor into IND-enabling studies in 2023.

Our Strategy

Our goal is to be the leading biopharmaceutical company leveraging proteomic and phosphoproteomic data, which we access through our proprietary AP3 platform, to unlock insights beyond genomic based approaches and discover and efficiently develop medicines to benefit patients with cancer.

The key elements of our strategy summarized below are to:

- Advance ACR-368, our CHK1/2 inhibitor, through clinical development in ovarian, bladder, and endometrial cancer by enrolling ACR-368 OncoSignature-positive patients.
- Selectively pursue AP3 identified rational drug combinations with our drug candidates in OncoSignature-negative patients, initially ACR-368 with low-dose gemcitabine.
- Discover and develop a pipeline of proprietary drug candidates by leveraging our AP3 platform and predictive OncoSignature tests.
- Acquire rights to drug candidates for which we believe our OncoSignature tests can increase the likelihood of clinical success.
- Opportunistically enter into strategic co-development partnerships around predictive OncoSignature tests to maximize the full potential of our AP3 platform.

Our Team

We were founded and are led by pioneers in oncogenic signaling, oncology precision medicine and the use of proteomic technology to uncover intracellular biochemical signaling pathways with the goal of applying this knowledge to develop drug candidates and clinical diagnostics. Our founders have pioneered and established proof-of-concept, including clinical implementation, for the underlying technologies in our AP3 platform. Our scientific advisors are thought leaders from leading global cancer and academic centers and are actively involved in our drug development process. We are supported by leading healthcare investors, Wellington Management, Surveyor Capital, RA Capital, Perceptive Advisors, Sands Capital and Chione. Prospective investors should not rely on the past investment decisions of our investors, as our investors may have different risk tolerances and have received their shares in prior offerings at prices lower than the price offered to the public in this offering.

Risks Associated with Our Business

Our business 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” and include, among others:

- We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

- We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- Even if this offering is successful, we will need additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned longer-term operations and the pursuit of our growth strategy.
- We are highly dependent on the success of our lead drug candidate, ACR-368, as this is our first drug candidate being developed for clinical development and regulatory approval. We may never obtain approval for ACR-368 or any other drug candidate.
- Our business substantially depends upon the successful clinical development of drug candidates using our AP3 platform and OncoSignature companion diagnostics. If we are unable to obtain regulatory approval for, and successfully commercialize, drugs developed through the application of our AP3 platform and OncoSignature tests, our business may be materially harmed.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, on a timely basis or at all, our business will be substantially harmed.
- The successful clinical development of our drug candidates depends on the co-approval of the OncoSignature test as a companion diagnostic test. If we or our companion diagnostic collaborator are unable to obtain regulatory approval for our OncoSignature companion diagnostic tests for our drug candidates, we may not obtain regulatory approval and realize the commercial potential of our drug candidates.
- Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and contract research organizations, or CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.
- The targeted oncology space is competitive, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- Our success depends in part on our ability to obtain intellectual property rights for our proprietary technologies and drug candidates, as well as our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- We depend on intellectual property licensed from a third party and termination of this license could result in the loss of significant rights, which would harm our business.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

Recent Developments—Preliminary Balance of Cash, Cash Equivalents and Short-term Investments

We estimate that we had cash, cash equivalents and short-term investments of approximately $76.8 million as of September 30, 2022, which excludes cash of approximately $0.4 million as of that date that is restricted as to use.

Our actual consolidated financial results as of September 30, 2022 are not yet available. Our financial closing procedures for the nine months ended September 30, 2022 are not yet complete and, as a result, our final results upon completion of those procedures may differ materially from our preliminary estimates. The preliminary consolidated financial data presented above as of September 30, 2022 is not a comprehensive statement of our financial position or operating results; reflects our preliminary estimates based on information available as of the date of this prospectus; and is subject to change, and those changes may be material. Accordingly, you should not place undue reliance upon these preliminary estimates.

This preliminary consolidated financial data has been prepared by, and is the responsibility of, our management. PricewaterhouseCoopers LLP has not audited, reviewed, compiled or applied agreed-upon procedures with respect to this preliminary consolidated financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect 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, or the JOBS Act. For so long as we remain an emerging growth company, we may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- an exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, in the assessment of our internal control over financial reporting;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements.

We may take advantage of these provisions until the last day of the fiscal year ending after the fifth anniversary of the completion of this offering or such earlier time that we no longer qualify as an emerging growth company. We will cease to qualify as an emerging growth company on the date that is the earliest of: (1) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering, (2) the last day of the fiscal year in which we have more than $1.24 billion in total annual gross revenues, (3) the date on which we are deemed to be a "large accelerated filer" under the rules of the U.S. Securities and Exchange Commission or (4) the date on which we have issued more than $1.0 billion of non-convertible debt over the prior three-year period. We will be deemed to be a "large accelerated filer" at such time that we (a) have an

aggregate worldwide market value of our common stock held by non-affiliates of $700 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, for a period of at least 12 months and (c) have filed at least one annual report pursuant to the Exchange Act. We may choose to take advantage of some but not all of these reduced reporting burdens. We have taken advantage of certain reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than you might obtain from other public companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can 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 extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this prospectus may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

We are also a "smaller reporting company" as defined under the Exchange Act. We may continue to be a smaller reporting company for so long as either (i) the market value of our common stock held by non-affiliates is less than $250 million as of the last business day of our most recently completed second fiscal quarter or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700 million as of the last business day of our most recently completed second quarter. 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 with less than $100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Corporate Information

We were incorporated under the laws of the State of Delaware in March 2018. Our principal executive offices are located at 480 Arsenal Way, Suite 100, Watertown, Massachusetts 02472, and our telephone number is (617) 207-8979. Our website address is *www.acrivon.com*. The information contained on, or accessible through, our website is not incorporated by reference into this prospectus. We have included our website in this prospectus solely as an inactive textual reference.

THE OFFERING

Common stock offered by us	5,900,000 shares
Underwriters' option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to 885,000 additional shares.
Common stock to be outstanding immediately after this offering	18,809,823 shares (or 19,694,823 shares if the underwriters exercise in full their option to purchase additional shares)
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $90.4 million (or approximately $104.4 million if the underwriters exercise in full their option to purchase up to 885,000 additional shares of common stock), assuming an initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, (i) to fund the advancement of ACR-368, including chemistry manufacturing and controls, or CMC, and companion diagnostic development, in Phase 2 clinical trials across our three lead indications into potential registrational phase, pending the results and discussions with the FDA, as well as to potentially initiate Phase 2 trials in patients with HPV+ tumors, (ii) to complete IND-enabling studies for at least one of our preclinical programs and (iii) the remainder for continued development of our AP3 platform, other research and development activities, working capital and other general corporate purposes. See the section titled "Use of Proceeds" beginning for additional information.
Risk factors	You should read the section titled "Risk Factors" for a discussion of factors you should consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.
Nasdaq Global Market symbol	"ACRV"

The number of shares of our common stock to be outstanding after this offering is based on 12,909,823 shares of our common stock outstanding as of June 30, 2022, after giving effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 11,140,262 shares of common stock, and excludes:

- 2,072,851 shares of our common stock issuable upon the exercise of options outstanding as of June 30, 2022 under our 2019 Stock Incentive Plan, or the 2019 Plan, at a weighted-average exercise price of $2.85 per

share (of which (i) options to purchase an aggregate of 25,039 shares of common stock were exercised subsequent to June 30, 2022 and (ii) options to purchase an aggregate of 65,392 shares of common stock were canceled subsequent to June 30, 2022), which does not include options to purchase an aggregate of 166,259 shares of our common stock, at a weighted-average exercise price of $4.07 per share, that were granted subsequent to June 30, 2022;

- 1,003,666 shares of our common stock available for future issuance as of June 30, 2022 under the 2019 Plan, which shares will cease to be available for issuance under the 2019 Plan at the time our 2022 Equity Incentive Plan, or the 2022 Plan, becomes effective and will be added to, and become available for issuance under, the 2022 Plan;
- an additional 2,555,571 shares of our common stock reserved for future issuance under our 2022 Plan, which will become effective on the date of the underwriting agreement related to this offering (of which we will grant certain options to purchase shares of common stock at an exercise price equal to the initial public offering price and certain restricted stock units, as described in "Executive Compensation"), as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2022 Plan and any additional shares of our common stock that may become available under our 2022 Plan, as more fully described in "Executive Compensation—Equity Incentive Plans"; and
- 215,000 shares of our common stock reserved for future issuance under our 2022 Employee Stock Purchase Plan, or the ESPP, which will become effective on the date of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

Unless otherwise indicated, all information contained in this prospectus, including the number of shares of common stock that will be outstanding after this offering, assumes or gives effect to:

- the conversion of all outstanding shares of our preferred stock into 11,140,262 shares of our common stock, which will occur upon the closing of this offering;
- a 1-for-2.466 reverse stock split of our common stock effected on November 1, 2022;
- the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering;
- no exercise of the outstanding options referred to above after June 30, 2022; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. The summary condensed consolidated statements of operations data for the six months ended June 30, 2022 and 2021 and the condensed consolidated balance sheet data as of June 30, 2022 have been derived from our unaudited condensed consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. We have derived the consolidated statement of operations data for the years ended December 31, 2021 and 2020 from our audited consolidated financial statements appearing at the end of this prospectus. 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 the results that may be expected in any future period and the results for the six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the fiscal year ending December 31, 2022 or any other future period.

	Six Months Ended June 30,		Year Ended December 31,	
	2022	2021	2021	2020
	(in thousands, except share and per share data)			
Consolidated Statement of Operations Data:				
Operating Expenses:				
Research and development	$ 10,145	$ 8,448	$ 13,718	$ 1,870
General and administrative	2,992	795	2,466	1,298
Total operating expenses	13,137	9,243	16,184	3,168
Loss from operations	(13,137)	(9,243)	(16,184)	(3,168)
Other income (expense):				
Other income, net	97	41	21	32
Change in fair value of convertible notes	—	—	—	(2,099)
Change in fair value of preferred stock tranche rights	—	(50)	(50)	(71)
Change in fair value of anti-dilution right	—	(208)	(30)	—
Total other income (expense), net	97	(217)	(59)	(2,138)
Net loss and comprehensive loss	(13,040)	(9,460)	(16,243)	(5,306)
Net loss attributable to common stockholders – basic and diluted	$ (13,040)	$ (9,460)	$ (16,243)	$ (5,306)
Net loss per share – basic and diluted[1]	$ (7.37)	$ (5.50)	$ (9.32)	$ (3.70)
Weighted-average common stock outstanding – basic and diluted[1]	1,769,561	1,718,569	1,743,382	1,432,480
Pro forma net loss per share – basic and diluted[2]	$ (1.01)		$ (1.26)	
Pro forma weighted-average common stock outstanding – basic and diluted[2]	12,909,823		12,883,644	

(1) See Note 13 to our audited consolidated financial statements and Note 11 to our unaudited condensed consolidated financial statements appearing at the end of this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.

(2) Pro forma basic and diluted net loss per share attributable to common stockholders has been prepared to give effect to adjustments to our capital structure arising in connection with the completion of this offering

and is calculated by dividing pro forma net loss attributable to common stockholders by the pro forma weighted-average common shares outstanding for the period. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders is equal to net loss attributable to common stockholders. The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share for the six months ended June 30, 2022 and year ended December 31, 2021 have been prepared to reflect the conversion of all of the outstanding shares of our convertible preferred stock into an aggregate of 11,140,262 shares of our common stock as if the offering had occurred on January 1, 2021.

	As of June 30, 2022		
	Actual	Pro Forma[1]	Pro Forma, As Adjusted[2]
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 83,861	$ 83,861	$ 174,251
Working capital[3]	82,710	82,710	173,313
Total assets	94,996	94,996	185,162
Total liabilities	9,054	9,054	8,841
Convertible preferred stock	122,518	—	—
Total stockholder's (deficit) equity	(36,576)	85,942	176,321

(1) Gives effect to the conversion of all of the outstanding shares of our preferred stock into an aggregate of 11,140,262 shares of our common stock upon the closing of this offering.

(2) Gives further effect to the sale of 5,900,000 shares of common stock in this offering at an assumed initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting fees and commissions and estimated offering expenses payable by us. This pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $5.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and stockholders' equity by $15.8 million, assuming no change in the assumed initial public offering price per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes, before deciding whether to purchase shares of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since our inception, we have incurred significant losses, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were $16.2 million and $5.3 million for the year ended December 31, 2021 and 2020, respectively, and $13.0 million and $9.5 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $37.9 million. Since our inception, we have financed our operations with aggregate net proceeds of $119.8 million from the issuance of convertible notes and the sale of our Series A-1 convertible preferred stock and Series B convertible preferred stock. We have no products approved for commercialization and have never generated any revenue from product sales.

All of our drug candidates are still in clinical and preclinical testing. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue to conduct our ongoing clinical trials of ACR-368, as well as initiate and complete additional clinical trials of future drug candidates or current drug candidates in new indications or patient populations;
- continue to advance the preclinical development of our other drug candidates and our preclinical and discovery programs;
- seek regulatory approval for any drug candidates that successfully complete clinical trials;
- pursue marketing approvals and reimbursement for our drug candidates;
- manufacture material under current good manufacturing practices, or cGMP, for clinical trials and potential commercial sales at our contracted manufacturing facilities;
- develop, establish and validate our commercial-scale cGMP manufacturing process;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- establish, either alone or with a third party, a sales, marketing and distribution infrastructure and scale up external, or establish internal, manufacturing and distribution capabilities to commercialize any drug candidates for which we may obtain regulatory approval;
- hire and retain additional personnel, including research, clinical, development, manufacturing quality control, quality assurance, regulatory and scientific personnel;
- add operational, financial, corporate development, management information systems and administrative personnel, including personnel to support our product development and planned future commercialization efforts; and

- incur additional legal, accounting and other expenses in operating as a public company.

To date, we have not generated any revenue from the commercialization of any drug candidate. To become and remain profitable, we must succeed in developing and eventually commercializing drug candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, validating manufacturing processes, obtaining regulatory approval, and manufacturing, marketing and selling any drug candidates for which we may obtain regulatory approval, as well as discovering and developing additional drug candidates. All of our drug candidates are in clinical or preclinical development. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with drug candidate development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform clinical trials or preclinical studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our drug candidates, our expenses could increase.

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.

We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We commenced operations in March 2018, and our operations to date have been largely focused on organizing and staffing our company, business planning, raising capital, building our AP3 platform, developing our manufacturing capabilities and developing our clinical and preclinical drug candidates, including undertaking preclinical studies and conducting clinical trials. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization, and we may not be successful in doing so. Consequently, any predictions you make 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 products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research and clinical focus to a company, if any of our drug candidates are approved, capable of supporting commercial activities. We may not be successful in such a transition.

Even if this offering is successful, we will need additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned longer-term operations and the pursuit of our growth strategy.

Our operations have consumed substantial amounts of cash since inception, and we expect to continue to incur significant expenses and operating losses over the next several years as we continue to develop our drug candidate pipeline and, to a lesser extent, build out our manufacturing capabilities for our drug candidates, which, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that may not be commercially available for a number of years, if at all. If we obtain marketing approval for any drug candidates that we develop or otherwise acquire, we expect to incur significant commercialization expenses

related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of June 30, 2022, we had cash and cash equivalents of $83.9 million. We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents as of June 30, 2022, will be sufficient to fund our operating expenses and capital expenditure requirements at least into the fourth quarter of 2024. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We plan to use the net proceeds from this offering to fund the advancement of ACR-368, including chemistry, manufacturing and controls, or CMC, and companion diagnostic development, in Phase 2 clinical trials across our three lead indications into potential registrational phase, pending results and discussions with the FDA, as well as to potentially initiate Phase 2 trials in patients with HPV+ tumors, to complete IND-enabling studies for at least one of our preclinical programs and the remainder for continued development of our AP3 platform, other research and development activities, working capital and other general corporate purposes. The net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, may not be sufficient to fund any of our drug candidates through regulatory approval. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional drug candidates and changes in regulation. The timing and amount of our funding requirements will depend on many factors, including:

- the rate of progress in the development of ACR-368 and our other drug candidates;
- the scope, progress, results and costs of non-clinical studies, preclinical development, laboratory testing and clinical trials for ACR-368 and future drug candidates and associated development programs;
- the extent to which we develop, in-license or acquire other drug candidates and technologies in our pipeline;
- the scope, progress, results and costs as well as timing of process development and manufacturing scale-up and validation activities associated with ACR-368 and our future drug candidates and other programs as we advance them through preclinical and clinical development;
- the ability of our AP3 platform to identify patient responders;
- the number and development requirements of drug candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our drug candidates;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the timing and costs of securing sufficient capacity for commercial supply of our drug candidates, or the raw material components thereof;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive marketing approval;
- the costs necessary to obtain regulatory approvals, if any, for products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- 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;
- the continuation of our existing licensing and collaboration arrangements and entry into new collaborations and licensing arrangements, if at all;
- the need and ability to hire additional research, clinical, development, scientific and manufacturing personnel;

- the costs we incur in maintaining business operations;
- the need to implement additional internal systems and infrastructure;
- the effect of competing technological, product and market developments;
- the revenue, if any, received from commercial sales of our drug candidates for which we receive marketing approval;
- the costs of operating as a public company; and
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials, including a public health emergency, such as the COVID-19 pandemic, or geopolitical events, including the ongoing Russian invasion of Ukraine, and related sanctions against Russia.

We will require additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our drug candidates. Further, our ability to raise additional capital 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 Russian invasion of Ukraine and related sanctions against Russia, and the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private-party grants, debt financings and license and collaboration agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

Risks Related to the Design and Development of Our Drug Candidates

We are highly dependent on the success of our lead drug candidate, ACR-368, as this is our first drug candidate being developed for clinical development and regulatory approval. We may never obtain approval for ACR-368 or any other drug candidate.

Our future success is highly dependent on our ability to obtain regulatory approval for, and then successfully commercialize or identify a strategic partner to commercialize, our lead drug candidate, ACR-368. ACR-368 has been dosed in more than 400 patients at the RP2D in past single center and multi-center Phase 2 clinical trials. We have received clearance from the FDA for an IND application to advance ACR-368 in Phase 2 single arm

clinical trials conducted under the FDA program known as the master protocol. We currently have no products that are approved for sale in any jurisdiction. ACR-368 or any of our other future drug candidates may not achieve success in their clinical trials or obtain regulatory approval. If we do not obtain regulatory approval for ACR-368 and successfully commercialize ACR-368 in one or more indications or if we experience significant delays in doing so, we may never generate any revenue or become profitable.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of ACR-368 or other future drug candidates identified through the application of our AP3 platform and OncoSignature companion diagnostics. The success of ACR-368 or any other future drug candidate will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of ACR-368 and our future drug candidates to the satisfaction of the FDA and other regulatory agencies;
- the ability of our AP3 platform-based OncoSignature tests to identify patient responders;
- the AP3 platform may not work equally well for all therapeutic targets;
- our ability, or that of our collaborators, to develop and obtain clearance or approval of companion diagnostics, on a timely basis, or at all;
- receipt and related terms of marketing approvals from applicable regulatory authorities for ACR-368 and our future drug candidates, including the completion of any required post-marketing studies or trials;
- raising additional funds necessary to complete the clinical development of and commercialization of ACR-368;
- successfully identifying and developing, acquiring or in-licensing additional drug candidates to expand our pipeline;
- acceptance of an IND application by the FDA or other similar clinical trial applications from other regulatory authorities for clinical trials for future drug candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for ACR-368 and our future drug candidates and our OncoSignature companion diagnostics;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if approved, whether alone or in collaboration with third parties;
- acceptance of our products, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies available on the market or in development;
- obtaining and maintaining third-party payor coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of any products following regulatory approval.

Many of these factors are beyond our control, and it is possible that none of our drug candidates, including ACR-368, will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we experience significant delays or are otherwise unable to successfully commercialize our drug candidates, it would materially harm our business.

Our business substantially depends upon the successful clinical development of drug candidates using our AP3 platform and OncoSignature companion diagnostics. If we are unable to obtain regulatory approval for, and successfully commercialize, drugs developed through the application of our AP3 platform and OncoSignature tests, our business may be materially harmed.

Using our AP3 platform, we have developed predictive OncoSignature tests for our clinical drug candidate, ACR-368, as well as for two other clinical stage drug candidates. Negative results in the development of ACR-368 may also impact our ability to successfully develop other drug candidates, either at all or within anticipated timeframes because, although other drug candidates may target different indications, the underlying technology platform, and specifically the use of an OncoSignature test, to identify patient responders is the same for all of our drug candidates. Accordingly, a failure in any one program may decrease trust in our AP3 program. In addition, if ACR-368 shows unexpected adverse events or a lack of efficacy in the indications we intend to treat, or if we experience other regulatory or developmental issues, our development plans and business could be significantly harmed. We cannot guarantee the successful clinical development, approval and commercialization of ACR-368.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, on a timely basis or at all, our business will be substantially harmed.

Our lead drug candidate is currently in Phase 2 clinical development under a master protocol designed for expedited drug development using our ACR-368 OncoSignature test. Although we are using our OncoSignature test to specifically treat patients predicted to be sensitive to ACR-368, we cannot guarantee that we will achieve sufficient ORR for marketing approval. For our preclinical drug candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidate in humans before obtaining marketing approval from regulatory authorities. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome.

The length of time necessary to complete clinical trials and to submit an application for marketing approval for a decision by a regulatory authority may be difficult to predict. The clinical trial requirements of the FDA and other comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a drug candidate vary substantially according to the type, complexity, novelty and intended use and market of the drug candidate. As a result, the regulatory approval process for drug candidates such as ours is uncertain and may be more expensive and take longer than the approval process for drug candidates based on other, better known or more extensively studied technologies. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our drug candidates in either the United States or other comparable regions of the world or how long it will take to commercialize our drug candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential drug candidate to market would adversely affect our business, financial condition, results of operations and prospects.

Our drug candidates, including ACR-368, could 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 drug 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 drug candidate’s clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of a New Drug Application, or NDA, to the FDA 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 the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- we or third-party collaborators may fail to obtain regulatory approval of companion diagnostic tests, if required, on a timely basis, or at all; 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.

Prior to obtaining approval to commercialize a drug candidate in the United States or elsewhere, we or our collaborators must demonstrate with substantial evidence from one or more well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory agencies, that such drug candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our drug candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our drug candidates either prior to or post-approval, or it may object to elements of our clinical development program. Depending on the extent of these or any other studies required by the FDA or comparable foreign regulatory authorities, approval of any regulatory approval applications that we submit may be delayed by several years, or may require us to expend significantly more resources than we have available.

Of the large number of potential products in development, only a small percentage successfully complete the FDA or comparable 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 drug candidates, which would significantly harm our business, results of operations and prospects.

Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. 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. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, 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 United States may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a post-marketing risk management strategy such as a Risk Evaluation and Mitigation Strategy, or REMS, or the equivalent in another jurisdiction. Regulatory authorities 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 drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

Depending on our clinical trial results, we may seek NDA approval for ACR-368 in the United States under the FDA's accelerated approval pathway, but this pathway may not lead to faster development, regulatory review, or approval process and does not increase the likelihood that ACR-368 will receiving marketing approval.

Depending on our clinical trial results, we intend to seek approval for ACR-368 for one or more indications, and we may seek approval of our future drug candidates, where applicable, under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition, generally provides a meaningful advantage over available therapies, and demonstrates 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. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as IMM. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new product over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct adequate and well-controlled post-marketing clinical trials to confirm the product's clinical benefit. These confirmatory trials must be completed with due diligence. If the sponsor fails to conduct such studies in a timely manner, or if such post-approval studies fail to verify the product's predicted clinical benefit, the FDA may withdraw its approval of the product on an expedited basis. In addition, for products being considered for accelerated approval, the FDA currently requires, unless otherwise informed by the Agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. There can be no assurance that the FDA would allow ACR-368 or any of the drug candidates we may develop to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, there can be no assurance that expedited development will occur or that the FDA will review and approve such submission or application on a timely basis, or at all. Moreover, even if we received accelerated approval, any post-marketing studies required to confirm clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and/or commercialization of ACR-368 or our other future drug candidates identified through the application of our AP3 platform and OncoSignature companion diagnostics.

Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly increase our product development costs. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize

ACR-368 or our future drug candidates identified through the application of our AP3 platform and OncoSignature companion diagnostics, including:

- regulators, institutional review boards, or IRBs, or ethics committees, or ECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA may disagree as to the design or implementation of our clinical trials or with our recommended doses with respect to ACR-368, or any of our future drug candidates;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective contract research organizations, or CROs, and prospective trial sites;
- clinical trials for ACR-368 or our future drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay or halt clinical trials or abandon product development programs;
- lack of adequate funding to continue clinical trials;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or may be lower than we anticipate due to challenges in recruiting and enrolling suitable patients who meet the trial criteria, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials;
- we may experience difficulties in maintaining contact with patients after treatment, resulting in incomplete data;
- we or third-party collaborators may fail to obtain regulatory approval of companion diagnostic tests, if required, on a timely basis, or at all;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for various reasons, including a finding by us or by a Data Monitoring Committee for a trial that the participants are being exposed to unacceptable health risks;
- ACR-368 or our future drug candidates may have undesirable or unexpected side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ECs to suspend or terminate the trials;
- the cost of clinical trials may be greater than we anticipate;
- changes to clinical trial protocols;
- the supply or quality of ACR-368 or our future drug candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials; and
- the impact of the ongoing COVID-19 pandemic, which may slow potential enrollment, reduce the number of eligible patients for clinical trials, or reduce the number of patients who remain in our trials.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial or obtain timely marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, the FDA may place a partial or full clinical hold on any of our current or future clinical trials for a variety of reasons, including safety concerns and noncompliance with

regulatory requirements. If we are not able to complete successful clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize ACR-368 or our future drug candidates.

Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates, which would limit our future revenues and harm our commercial prospects.

The successful clinical development of our drug candidates depends on the co-approval of the OncoSignature test as a companion diagnostic test. If we or our companion diagnostic collaborator are unable to obtain regulatory approval for our OncoSignature companion diagnostic tests for our drug candidates, we may not obtain regulatory approval and realize the commercial potential of our drug candidates.

A key part of our development strategy for our drug candidates is to identify subsets of patients with specific types of tumors. Identification of these patients will require the use and development of companion diagnostics. According to the FDA's 2014 guidance document on In Vitro Companion Diagnostic Devices, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the premarket application for the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co-development of an in vitro companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding in vitro companion diagnostic.

We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on our collaboration partner Akoya to perform these functions. Akoya has not commercialized or submitted or obtained Premarket Approval Application, or PMA, for any companion diagnostic, and any setbacks they encounter could delay any commercial launch of ACR-368, if approved. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a drug candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our drug candidates, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our drug candidates, or experience delays in doing so, the development of these drug candidates may be adversely affected, these drug candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that have or may obtain marketing approval. We may not be able to enter into arrangements with another diagnostic company to develop and obtain regulatory approval for an alternative diagnostic test for use in connection with the development and commercialization of our drug candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic candidates or therapeutics.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and will likely require separate regulatory approval prior to commercialization. If we or third parties are unable to successfully develop companion diagnostics for our drug candidates, or experience delays in doing so:

- the development of these drug candidates may be delayed because it may be difficult to identify patients for enrollment in our clinical trials in a timely manner;

- these drug candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of these drug candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients or types of tumors targeted by these drug candidates.

Even if our drug candidates and any associated companion diagnostics are approved for marketing, the need for companion diagnostics may slow or limit adoption of our drug candidates. Although we believe companion diagnostic testing is becoming more prevalent in the diagnosis and treatment of cancer, our drug candidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic or the need to complete additional testing prior to administering our drug candidates.

If any of these events were to occur, our business and growth prospects would be harmed materially.

We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

Although we received clearance from the FDA for an IND to advance ACR-368 in Phase 2 single arm clinical trials conducted under the master protocol, we may not be able to file INDs for our other drug candidates on the timelines we expect. For example, we may experience, or our partners may experience, manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our ongoing or planned clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. In addition, some of our competitors currently have ongoing clinical trials for drug candidates that would treat the same patients as our lead clinical drug candidate, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates. We rely on our external companion diagnostic partner, Akoya, to perform ACR-368 OncoSignature testing in our clinical trial. If Akoya encounters delays or technical challenges, enrollment in our clinical trials may be substantially delayed. Patient enrollment is also affected by other factors, including:

- the severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;
- competing studies or trials with similar eligibility criteria;
- invasive procedures required to enroll patients and to obtain evidence of the drug candidates' performance during clinical trials;
- availability and efficacy of approved medications for the disease under investigation;

- eligibility criteria defined in the protocol for the trial in question;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;
- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials, including due to the COVID-19 pandemic, may result in increased development costs, which would cause the value of our company to decline, limit our ability to obtain additional financing and delay or limit our ability to obtain regulatory approval for our drug candidates.

Unexpected adverse side effects or other safety risks associated with ACR-368 or our other future drug candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved product or result in significant negative consequences following marketing approval, if any.

As is the case with small molecule therapeutics generally, side effects and adverse events associated with ACR-368 have been observed. Although ACR-368 has been evaluated in approximately 1,000 patients in clinical trials to date with a generally favorable tolerability profile, unexpected side effects may still arise in our ongoing or any future clinical trial.

Our trials will be primarily based on the established RP2D dosing regimen used in over 400 patients in past trials. In these trials, the most frequent treatment related adverse events greater than or equal to Grade 3, which are considered serious adverse events, were primarily reversible, manageable hematological toxicities, including neutropenia and thrombocytopenia and there was only limited non-hematological toxicities. In one of the clinical trials (a cohort of 58 platinum-sensitive patients), there were three deaths deemed possibly related to study treatment. In addition, our trials will also, in part, include testing of ACR-368 at RP2D in combination with low dose gemcitabine, which could result in greater severity and prevalence of side effects or unexpected characteristics. Undesirable side effects could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our drug candidates or those of our competitors may only be uncovered with a significantly larger number of patients exposed to the drug.

Additionally, due to the high mortality rates of the cancers for which we are initially pursuing development and the pretreated and advanced nature of disease in many patients in our ongoing clinical trials of ACR-368, a material percentage of patients in these clinical trials ultimately will die during a trial for reasons unrelated to the drug. For example, in the Phase 1b/2 combination arm of our Phase 2 trial for ACR-368 we recently dosed a patient who had previously failed three lines of prior therapy. The patient died prior to receiving a second dose of ACR-368 and the death was determined by the trial investigator not to be drug related, but instead related to the subject's disease progression. If we elect to, or are required to, delay, suspend or terminate any clinical trial, whether due to a patient death or otherwise, the commercial prospects of ACR-368 or our future drug candidates could be harmed and our ability to generate product revenues could potentially be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of our drug candidates, which would harm our commercial prospects our financial condition and our reputation.

Moreover, if ACR-368 or any of our future drug candidates are 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 drug candidate, even if it is approved. We may also be required to modify our trial plans based on findings in our clinical trials. Side effects could also affect patient recruitment or the ability of enrolled patients to complete a trial. Many drugs that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions, require additional testing to confirm these determinations, require more restrictive labeling or deny regulatory approval of the drug candidate.

It is possible that, as we test our drug candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our drug candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, if ACR-368 receives marketing approval, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the drug;
- we may be required to recall a product or change the way the drug is administered to patients;
- regulatory authorities may require additional warnings in the labeling, such as a contraindication 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 required to implement a REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- we may be subject to regulatory investigations and government enforcement actions;
- the drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our drug candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Preliminary, interim and topline data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and is 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 topline data from our clinical trials, such as futility analyses, ORR, or various primary and secondary clinical endpoints. These updates will be 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. Additionally,

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 becomes available. Therefore, positive interim results in any ongoing clinical trial may not be predictive of such results in the completed 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 topline 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 has been received and fully evaluated. Topline data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data is available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Adverse changes between preliminary or interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock after this offering. See the description of risks under the heading "Risks Related to our Common Stock and This Offering" for more disclosure related to the risk of volatility in our stock price.

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 drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is 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, drug candidate or our business.

Additionally, other future clinical trials we conduct may be open-label trials in which both the patient and investigator know whether the patient is receiving the investigational drug candidate or either an existing approved product or placebo. Open-label clinical trials typically test only the investigational drug 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.

If the preliminary or topline data that we report differs 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, ACR-368, or any other future drug candidates may be harmed.

We may in the future seek to engage in strategic transactions to acquire or in-license additional products, drug candidates or technologies. If we are unable to realize the benefits from such transactions, it may adversely affect our ability to develop and commercialize an expanded pipeline of drug candidates, negatively impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, joint ventures and in-licensing of new products, drug candidates or technologies that we believe will complement or augment our existing business. For example, in 2021, we acquired our lead drug candidate, ACR-368, pursuant to worldwide license agreement with Lilly which maintains certain open INDs with the FDA for prexasertib being supplied to investigator-initiated studies. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to

successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

Following any such strategic transaction, we may not achieve any expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near-term and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including, but not limited to, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, drug candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the transaction or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our drug candidates and could have a negative impact on the competitiveness of any drug candidate that reaches market.

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other future drug candidates or for other indications that later prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to that drug candidate.

Our clinical development is focused on the development of precision oncology medicines utilizing our proprietary precision medicine platform, which is based on a novel scientific approach and may never lead to marketable products.

The development of precision oncology medicines for patients whose tumors are sensitive to a specific product or drug candidate based on direct protein measurement is a rapidly emerging field, and the scientific discoveries that form the basis for our efforts to develop drug candidates are relatively new. Furthermore, our OncoSignature companion diagnostic is based on new technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

The scientific evidence to support the feasibility of developing drug candidates based on these discoveries is both preliminary and limited. Although we believe, based on our clinical work, that our approach is applicable

across stages of drug development and therapeutic modalities, clinical results may not confirm this hypothesis or may only confirm it for certain tumor types. Therefore, we do not know if our approach will be successful, but if our approach is unsuccessful, our business will suffer.

Efforts to identify, acquire or in-license, and then develop drug candidates require substantial technical, financial and human resources, whether or not any drug candidates are ultimately identified. We apply our AP3 platform and OncoSignature companion diagnostic in our efforts to discover potential precision targets for which drug candidates may be developed. Our efforts may initially show promise in identifying potential drug candidates, yet fail to yield drug candidates for clinical development, approved products or commercial revenues for many reasons, including the following:

- the methodology used may not be successful in identifying potential drug candidates;
- competitors may develop alternatives that render any drug candidates we develop obsolete;
- any drug candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a drug candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a drug candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a drug candidate may not be accepted as safe and effective by physicians, patients, the medical community or third-party payors.

Increasing demand for compassionate use of our drug candidates could negatively affect our reputation and harm our business.

We are developing drug candidates for the treatment of indications for which there are currently limited or no available therapeutic options. It is possible for individuals or groups to target companies with disruptive social media campaigns related to a request for access to unapproved drugs for patients with significant unmet medical need. If we experience a similar social media campaign regarding our decision to provide or not provide access to any of our current or future drug candidates under an expanded access policy, our reputation may be negatively affected and our business may be harmed.

Recent media attention to individual patients' expanded access requests has resulted in the introduction and enactment of legislation at the local and national level referred to as "Right to Try" laws, such as the federal Right to Try Act of 2017 signed into law on May 30, 2018, which are intended to allow patients access to unapproved therapies earlier than traditional expanded access programs. A possible consequence of both activism and legislation in this area may be the need for us to initiate an unanticipated expanded access program or to make our drug candidates more widely available sooner than anticipated.

In addition, some patients who receive access to drugs prior to their commercial approval through compassionate use, expanded access programs or right to try access have life-threatening illnesses and have exhausted all other available therapies. The risk for serious adverse events in this patient population is high, which could have a negative impact on the safety profile of our drug candidates if we were to provide them to these patients, which could cause significant delays or an inability to successfully commercialize our drug candidates, which could materially harm our business. If we were to provide patients with any of our drug candidates under an expanded access program, we may in the future need to restructure or pause any compassionate use and/or expanded access programs for a variety of reasons, which could prompt adverse publicity or other disruptions related to current or potential participants in such programs.

Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business and operations may be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared by the World Health Organization as a global pandemic, including the current resurgences as a result of the Omicron variant and related subvariants in various regions in the United States and globally and other future resurgences. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including public health directives and orders in the United States and globally that, among other things and for various periods of time, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel. Future remote work policies and similar government orders or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity; disrupt our ongoing research and development activities and our clinical programs and timelines; and cause disruptions to our supply chain, to the administrative functions of clinical trial sites and to the operations of our other partners, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In the event that government authorities were to enhance current restrictions, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities. We may also face difficulties in obtaining access to manufacturing slots for our drug candidates.

Although our ongoing and planned clinical trials have not been impacted by the COVID-19 pandemic to date, we may experience related disruptions in the future that could severely impact our clinical trials, including:

- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays, difficulties or interruptions in shipping and delivering in a timely manner supplies, samples or products required for our clinical trials due to the impact of the ongoing COVID-19 pandemic on the United States Postal Service, FedEx, United Parcel Service and/or other commercial shipping organizations;
- delays, difficulties or interruptions in obtaining the raw materials and other resources needed for our operations, including due to government-led diversion, reprioritization or appropriation of such resources;
- delays or interruptions in third-party or collaborator services, including due to government-led diversion, reprioritization or appropriation of such services;
- interruptions in our ability to manufacture and deliver drug supply for trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- changes in local regulations as part of a response to the ongoing COVID-19 pandemic that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in these affected geographies.

The spread of COVID-19, including new variants of the virus, such as the Omicron variant and related subvariants, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Since the beginning of the COVID-19 pandemic, several vaccines for COVID-19 have received Emergency Use Authorization by the FDA and a number of those later received marketing approval. Additional vaccines may be authorized or approved 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 and/or more costly to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this prospectus, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat patients with the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects. In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

Risks Related to Government Regulation

Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals 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 in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for 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. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA, signed into law in 2010, provides that 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;

- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and the federal civil monetary penalty law which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the United States federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. 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 implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on health plans, healthcare clearinghouses and certain healthcare providers, known as "covered entities", and their respective HIPAA "business associates", which are independent contractors that perform certain services for or on behalf of covered entities or other business associates involving the use or disclosure 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 HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with specific exceptions, to report annually to Centers for Medicare & Medicaid Services, or CMS, information

related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (such as physicians assistants and nurse practitioners), and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; and

- state and foreign laws and regulations that are analogous to each of the above federal laws; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain FDA approval of any of our drug candidates in the United States, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and

increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any drug candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

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

Any drug candidate for which we obtain marketing approval will be subject to ongoing regulatory requirements for, among other things, manufacturing processes, submission of post-approval clinical data and safety information, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, promotional activities and product tracking and tracing. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that we conduct post-approval.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug and biologic products, including requirements pertaining to their marketing and promotion in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our products for uses beyond their approved diseases, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act, relating to the promotion of prescription drugs for unapproved uses may lead to enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, 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 yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters, or holds on clinical trials;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;

- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies, and the policies of foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, executive orders or other actions could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. If such executive actions were to impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business could be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Enacted and future healthcare legislation may increase the difficulty and cost for us to progress our clinical programs and obtain marketing approval of and commercialize our drug candidates and may affect the prices we may set.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the health reform measures of the Biden administration will impact the ACA and our business.

In addition, 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, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute will remain in effect until 2031 unless additional action is taken by Congress. However, pursuant to COVID-19 relief legislation, these Medicare sequester reductions were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester .In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. presidential executive orders, Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering drug pricing and other health reform initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures and could negatively affect our customers and accordingly, our financial operations.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare 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 healthcare programs. This could reduce the ultimate demand for our drug candidates or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our drug candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. 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 health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to commercialize our drug candidates, if approved.

In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption

of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our drug candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

If we or our third-party manufacturers and suppliers 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. Although we do not currently manufacture our drug products or drug candidates on site, our research and development activities do involve the use of biological and hazardous materials and produce hazardous waste products at small quantities. 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, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Our business depends upon the ability of the FDA to accept and review our potential regulatory filings. If a prolonged government shutdown occurs, it could significantly impact the ability

of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our ability to advance clinical development of our drug candidates.

If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future shutdowns of other government agencies, such as the U.S. Securities and Exchange Commission, or SEC, may also impact our business through review of our public filings and our ability to access the public markets.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could adversely affect our business.

If ACR-368 or any of our other drug candidates are approved for commercialization, we may seek to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we would be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug and companion diagnostic approvals and rules governing drug and companion diagnostic commercialization in foreign countries;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability;
- greater difficulty with enforcing our contracts;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by individual countries in Europe with which we will need to comply. If we are unable to successfully manage the challenges of international expansion and operations, our business and operating results could be harmed.

We may develop our current and future drug candidates in combination with other therapies, and safety or supply issues with combination-use products may delay or prevent development and approval of our drug candidates.

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

would be subject to similar risks if we develop any of our drug candidates for use in combination with other drugs or for indications other than cancer. Similarly, if the therapies we use in combination with our drug candidates are replaced as the standard of care for the indications we choose for any of our drug candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We may also evaluate our drug candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or a similar regulatory authority outside of the United States. We may be unable to effectively identify and collaborate with third parties for the evaluation of our drug candidates in combination with their therapies. We will not be able to market and sell any drug candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. The regulations prohibiting the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. In addition, there are additional risks similar to the ones described for our products currently in development and clinical trials that result from the fact that such cancer therapies are unapproved, such as the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or a similar regulatory authority outside of the United States does not approve these other drugs or revokes approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any drug candidate we develop, we may be unable to obtain approval of or market such product.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat patients with a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing the drug for the type of disease or condition will be recovered from sales of the product 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. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in certain circumstances, such as a showing of clinical superiority (i.e., another product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity.

ACR-368 has been granted orphan drug designation, or ODD, for the treatment of anal cancer. We may apply for an ODD in the United States or other geographies for ACR-368 for the treatment of other diseases or conditions or for our future drug candidates. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so. Even if we obtain orphan drug designation for a drug candidate in specific indications, we may not be the first to obtain regulatory approval of the drug candidate for the orphan-designated indication, due to the uncertainties associated with developing drug products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for orphan 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. Orphan drug designation does not ensure that we will receive

marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other future drug candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

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

At various times, we may seek Fast Track designation for one or more of our drug candidates. If a drug candidate is intended for the treatment of a serious or life-threatening condition and the drug candidate demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for our lead drug candidate and/or certain of our future drug candidates, but there is no assurance that the FDA will grant this status to any of our proposed drug candidates and we might only be successful in receiving a Fast Track designation from the FDA for a drug candidate after applying on more than one occasion. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the receipt of a Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant a Fast Track designation, so even if we believe a particular drug candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive a Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw a Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

A Breakthrough Therapy designation by the FDA, even if granted for any of our current or future drug candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our drug candidates will receive marketing approval.

We may seek Breakthrough Therapy designation for our lead drug candidate and some or all of our future drug candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drug 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. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe a drug candidate meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such a designation. In any event, the receipt of a Breakthrough Therapy designation for a drug candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA of a drug candidate. In addition, even if a drug candidate qualifies as a Breakthrough Therapy, the FDA may later decide that the drug candidate no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for our lead drug candidate and some or all of our future drug candidates for the treatment of various cancers, there can be no assurance that we will receive Breakthrough Therapy designations.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third party contractors and CROs are required to comply with good laboratory practices, or GLPs, as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with drug products produced in compliance with applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process.

Further, these laboratories, investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our drug candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our drug candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any drug candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional laboratories or CROs or investigators involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO

commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage drug candidate or any future drug candidates.

We rely on third parties to supply and manufacture our drug candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such drug candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of drug candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance.

We do not currently have the infrastructure or capability internally to manufacture all our drug candidates for use in the conduct of our preclinical studies and clinical trials or for commercial supply, if our products are approved. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. This could be particularly problematic if we rely on a single-source supplier. Reliance on third-party providers may expose us to more risk than if we were to manufacture our drug candidates ourselves. We are dependent on our CMOs for the production of our drug candidates in accordance with relevant regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

Our third-party manufacturers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, war, disease outbreaks or public health pandemics, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for any of our drug candidates, we could experience delays in our research or ongoing and planned clinical trials or commercialization. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes who could meet our timelines at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, could significantly delay our preclinical studies, our clinical trials and the commercialization of our products, if approved, which could materially adversely affect our business, financial condition and results of operation.

In complying with the applicable manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We

and any of these third-party suppliers may also be subject to audits by the FDA and comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on CMOs, as any disruption, such as a fire, natural hazards, vandalism or an outbreak of contagious disease affecting the CMO or any supplier of the CMO could significantly interrupt our manufacturing capability. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as the CMO builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all.

Our current and future partnerships will be important to our business. If we are unable to enter into new partnerships, or if these partnerships are not successful, our business could be adversely affected.

We have existing partnerships and license agreements, including with Lilly for ACR-368 and with Akoya to co-develop, validate and commercialize our OncoSignature test. Moreover, a part of our business strategy is to carefully evaluate and, as deemed appropriate, potentially enter into partnerships in the future, including with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into partnerships with other companies to provide us with additional drug candidates and funding for our programs and AP3 platform. If we fail to enter into or maintain partnerships on reasonable terms or at all, our ability to develop our existing or future research programs and drug candidates or to identify future drug candidates through the application of our AP3 platform and OncoSignature companion diagnostics could be delayed, the commercial potential of our product could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

Our current partnerships, and any partnerships we may enter into in the future, may pose a number of risks, including, but not limited to, the following:

- partners have significant discretion in determining the efforts and resources that they will apply;
- partners may not perform their obligations as expected;
- partners could independently develop, or develop with third parties, products that compete directly or indirectly with our products and drug candidates if the partners believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- partners may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a drug candidate or product;
- disagreements with partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of drug candidates, might lead to additional responsibilities for us with respect to drug candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a partners of ours is involved in a business combination, the partner might deemphasize or terminate the development or commercialization of any drug candidate licensed to it by us; and

- partnerships may be terminated by the partner, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable drug candidates.

If our partnerships do not result in the successful discovery, development and commercialization of drug candidates or if one of our partners terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such partnership.

All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our partners. Additionally, if one of our partners terminates its agreement with us, we may find it more difficult to attract new partners and our perception in the business and financial communities could be adversely affected.

We may not be able to negotiate partnerships on a timely basis, on acceptable terms, or at all. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the partner's resources and expertise, the terms and conditions of the proposed partnership and the proposed partner's evaluation of a number of factors. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The partner may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

Risks Related to Commercialization of Our Drug Candidates

Even if any of our current or drug candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If ACR-368 or our future drug candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments, such as existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- the acceptance of our drug candidates as front-line treatments for various indications;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the size of the target patient population;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the strength of marketing and distribution support;

- publicity for our drug candidates and competing products and treatments;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, then our revenue potential and ability to achieve profitability will be adversely affected.

The total addressable market opportunity for ACR-368 and any other future drug candidates we may develop will ultimately depend upon, among other things, the proportion of patients identified as sensitive to our treatments based on our OncoSignature tests in our target indications, acceptance by the medical community, patient access, drug and any related companion diagnostic pricing and their reimbursement.

We may initially seek regulatory approval of ACR-368 or our future drug candidates as therapies for patients with platinum-resistant ovarian, bladder or endometrial cancer. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We currently have no marketing and sales organization and may have to invest significant resources to develop these capabilities. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate revenue.

We currently have no sales or marketing infrastructure or experience in the sale, marketing or distribution of drug products. Our operations to date have been focused on developing and extensively evaluating in preclinical studies our AP3 platform and our proprietary predictive OncoSignature tests, acquiring the rights to ACR-368, advancing our preclinical drug candidate programs, organizing and staffing our company, business planning and raising capital. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties.

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to raise financing necessary to build our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products;
- unfavorable third-party payor coverage and reimbursement in any geography;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Furthermore, developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our drug candidate. We may not be able to build an effective sales and marketing organization in the United States, the European Union 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 drug candidate, we may have difficulties generating revenue from them.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues and our profitability, if any, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our drug candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any drug candidate for which we receive marketing approval.

The targeted oncology space is competitive, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of drug products is highly competitive. We face competition with respect to our current drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide.

We anticipate several biopharmaceutical companies will aim to develop precision oncology approaches for the larger subsets of cancers where genetics has proven insufficient for patient responder identification over the next decade. We expect that the broader biopharmaceutical field will eventually recognize proteomics as the next era of precision medicine. We are aware of several competitors with CHK1/2 inhibitors and WEE1 inhibitors, including Sierra Oncology (SRA737), Astrazeneca/Merck (Adavosertib), Zentalis (Zn-c3), Debiopharm (Debio0123), Impact Therapeutics (IMP7068) and Shouya Holdings (SY-4835), and one company with a PKMYT1 inhibitor, Repare Therapeutics (RP-6306).

Many of the companies against which we are competing or against which we may compete in the future, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While ACR-368 or our future drug

candidates, if approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our drug candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of, and gaining significant share of the market for, our drug candidates may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as drug candidates progress through clinical development.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable labeling than ACR-368 or our future drug candidates. Our competitors also may obtain FDA, foreign regulatory authority, or other marketing or regulatory approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, thereby limiting our potential for commercial success.

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

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if such drug candidates obtain marketing approval.

Our ability to commercialize any drug candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs, private health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, which decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow CMS's decisions regarding coverage and reimbursement.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. 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. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any drug candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If

coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

Additionally, companion diagnostic tests will be required to obtain coverage and reimbursement separate and apart from the coverage and reimbursement we seek for our drug candidates, if approved.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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 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 drug 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.

The market opportunities for any current or future drug candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

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

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

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against any claims that our drug candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- diversion of management and scientific resources from our business operations;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of ACR-368 or our future drug candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A successful product liability claim or series of claims brought against us could decrease our cash and adversely affect our business and financial condition.

Risks Related to Employee Matters and Our Operations

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

We are highly dependent on the management, development, clinical, financial and business development expertise of our executive officers, particularly Peter Blume-Jensen, M.D., Ph.D., our co-founder, President and CEO, the inventor of our AP3 platform and OncoSignature patient selection method and a member of our board of directors and Kristina Masson, Ph.D., our co-founder and President and CEO of our phosphoproteomics subsidiary in Lund, Sweden. Each of our executive officers may currently terminate their employment with us at any time. We do not currently maintain "key person" insurance for any of our executives or employees.

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

universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our 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.

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

As of October 31, 2022, we had 39 full-time employees and three part-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, regulatory affairs and, if any of our drug candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our choice to focus on multiple therapeutic areas may negatively affect our ability to develop adequately the specialized capability and expertise necessary for operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

Our endeavors to properly classify our employees as exempt or non-exempt with respect to wage and hour laws, including, but not limited to, for purposes of minimum wage, overtime and applicable meal and rest periods, and we monitor and evaluate such classifications. Although there are no current, pending, or threatened claims or investigations against us asserting that any employees have been incorrectly classified as exempt, the possibility nevertheless exists that certain job roles could be deemed to have been incorrectly classified as exempt. In addition, we endeavor to classify our workforce properly, and we monitor and evaluate such classifications. Although there are no current, pending, or threatened claims or investigations against us asserting that any independent contractors have been incorrectly classified, the possibility nevertheless exists that certain contractors could be deemed to be employees

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, 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. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Our business and operations would suffer in the event of system failures, cyberattacks or a deficiency in our or our CROs', manufacturers' contractors', consultants' or collaborators' cybersecurity.

Despite the implementation of security measures, our internal computer systems, as well as those of third parties on which we rely, are vulnerable to damage from, among other things, computer viruses, malware, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures, system malfunctions, cyberattacks or cyber-intrusions over the Internet, attachments to emails, phishing attacks, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could lead to the loss, destruction, alteration, prevention of access to, disclosure, dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal data) or data that is processed or maintained on our behalf, and cause interruptions in our operations, which could result in a material disruption of our drug candidate development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, we cannot ensure that our information technology and infrastructure will prevent breakdowns or breaches in our or their systems or other cybersecurity incidents that cause loss, destruction, unavailability, alteration, dissemination of, or damage or unauthorized access to, our data, including personal data, assets and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, operations or financial condition. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay clinical development of our drug candidates.

To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information or personal data, we could incur material legal claims and liability and damage to our reputation, and the further development of our drug candidates could be delayed. Any such event could also compel us to comply with federal and state breach notification laws, and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us

to substantial liability under laws, rules, regulations and standards that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Notifications and follow-up actions related to a data breach or other security incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident. However, we cannot guarantee that we will be able to detect or prevent any such incidents, or that we can remediate any such incidents in an effective or timely manner. Our efforts to improve security and protect data from compromise may also identify previously undiscovered instances of data breaches or other cybersecurity incidents. To the extent that any data breach, disruption or security incident were to result in any loss, destruction, or alteration of, damage, unauthorized access to or inappropriate or unauthorized disclosure or dissemination of, our data, including personal data, or other information that is processed or maintained on our behalf, we could be exposed to litigation and governmental investigations and inquiries, the further development and commercialization of our drug candidates could be delayed and we could be subject to significant fines or penalties for any noncompliance with applicable state, federal and foreign privacy and security laws, rules, regulations and standards.

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

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we 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 drug candidates. Our ability to obtain clinical supplies of our drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

We are subject to a variety of privacy and data security laws, rules, regulations, policies, industry standards and contractual obligations, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

In Europe, the General Data Protection Regulation, or GDPR, took effect in May 2018. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area, or EEA, including clinical trial data. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data breaches to the competent national data processing authorities, requires having lawful bases on which personal data can be processed and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws; in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-U.S. Privacy Shield and imposing further restrictions on the use of standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue), and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Relatedly, following the United Kingdom's withdrawal from the EEA and the European Union and the expiration of the Transition Period, companies must comply with both the GDPR and the legislation similar to the GDPR as incorporated into UK national law, which provides for significant fines of up to the greater of £17.5 million or 4% of global turnover and exposes companies to two parallel regimes with potentially divergent enforcement actions for certain violations. On January 1, 2021, the United Kingdom became a third country for purposes of the GDPR. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example with respect to how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. Pursuant to the EU-UK Trade and Cooperation Agreement of December 24, 2020, transfers of personal data from the European Union to the United Kingdom may continue to take place without a need for additional safeguards during a further transition period, which expires on the earlier of (i) the date on which an adequacy decision with respect to the United Kingdom is adopted by the European Commission; or (ii) the expiry of four months, which shall be extended by a further two months unless either the European Union or the United Kingdom objects. On February 19, 2021 the European Commission published its draft decision finding the United Kingdom to be adequate under the GDPR, though it remains unclear whether the European Commission will formally adopt an adequacy decision with respect to the United Kingdom. In the absence of such decision, after the expiry of the additional transition period we may need to put in place additional safeguards for transfers of personal data from the European Union to the United Kingdom, such as standard contractual clauses approved by the European Commission.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt out of certain sales of personal information. 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. Further, the California Privacy Rights Act, or CPRA, recently passed in California and will impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and opt outs for certain

uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Although the CCPA currently exempts certain health-related information, including clinical trial data, the CCPA and the CPRA may increase our compliance costs and potential liability. Similar laws have been proposed in other states and at the federal level and, if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

With the GDPR, CCPA, CPRA and other laws, regulations and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. We are currently in the process of developing and updating our policies and procedures in accordance with requirements under applicable data privacy and protection laws and regulations. We do not currently have any formal data privacy policies and procedures in place and have not completed formal assessments of whether we are in compliance with all applicable data privacy laws and regulations. Additionally, if third parties with which we work, such as vendors or service providers, violate applicable laws, rules or regulations or our policies, such violations may also put our or our clinical trial and employee data, including personal data, at risk, which could in turn have an adverse effect on our business.

Risks Related to Intellectual Property

Our success depends in part on our ability to obtain intellectual property rights for our proprietary technologies and drug candidates, as well as our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our drug candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents, trademarks and trade secrets against third-party challenges or violations. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our technologies and drug candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technologies similar or identical to ours, and our ability to commercialize any drug candidates and technologies we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify, or to file on, patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering drug candidates and technologies that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our drug candidates, technologies or uses thereof in the United States or in other countries. Many of our technologies relate to diagnostics, such as for identifying subjects who are likely to respond to a particular drug due to biological characteristics of their tumors. Recent court decisions in the United States, such as *Athena Diagnostics v. Mayo Collaborative Services,* 915 F.3d 743 (Fed. Cir. 2019), *cert. denied,* 140 S. Ct. 855 (2020) have invalidated certain patents in the diagnostics space as covering laws of nature. Some or all of our technologies may similarly be found not eligible for patent protection.

Even if we do successfully issue patents that cover our products or technologies, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around or otherwise avoiding our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our drug candidates is insufficient or is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our drug candidates and our technologies.

Further, patents have limited terms. We may not be able to issue patents whose terms provide sufficient protection during the commercial lifetime of our drug candidates or of our technologies. For example, if we encounter delays in our clinical trials, the period of time during which we could market our drug candidates under patent protection could be reduced.

Some or all of our patents may have claims whose infringement is difficult to detect or to prove. Courts place the legal burden of proving infringement on patent holders. If we cannot convince a court that we have met this burden of proof, then our patent may not provide useful protection even if valid and enforceable against infringers.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our drug candidates or technologies. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications or issued patents (collectively, our "patent filings") and, if we are not, we may be subject to priority disputes or derivation challenges. We may be required to disclaim part or all of the term of certain patent filings. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court or patent office to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our drug candidates and technologies, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our drug candidates, our technologies or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around or otherwise avoid the claims of patents that we have had issued that cover our products and technologies.

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

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first to invent" to a

"first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a set of new patent office procedures for reviewing patents after issuance.

The degree of future protection for our intellectual property rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds or formulations similar or equivalent our drug candidates, or to develop technologies similar or comparable to ours, but that are not covered by the claims of any patents, should they issue, that we own or control;
- the active ingredients in our current drug candidates will eventually become commercially available in generic drug products, and is it possible that patent protection may not be available with regard to formulation or method of use;
- we or our licensors or collaborators, as the case may be, may fail to meet our obligations to the U.S. government in regards to any patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors or collaborators, as the case may be, might not have been the first to invent, or the first to file patent applications for our inventions, or may be found to have derived these inventions from others;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights in a way that we can detect and prove;
- it is possible that our pending patent applications will not result in issued patents in jurisdictions where we or our competitors operate commercially, in time to provide useful commercial protection, or at all;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products or technologies for sale in our major commercial markets;
- it is possible that there are prior public disclosures that could invalidate our patents or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technologies;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the extent required for us to benefit commercially, or at all;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our drug candidates or technologies;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges;
- we may not be able to detect or to prove infringement of our owned or in-licensed patents;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products or technologies to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- we may choose not to file for patent protection in order to maintain certain trade secrets, and a third party may subsequently obtain a patent covering such intellectual property;
- it is possible that drug candidates or technologies we develop may be covered by third parties' patents or other exclusive rights;
- the patents of others may have an adverse effect on our business;
- we may be unable to protect the confidentiality of key information, including trade secrets, that are required for us to achieve or maintain our business goals;
- we may not be able to detect breaches of confidentiality obligations to us before significant damage is done to our business; or
- we may not be able to build brand identity in the marks we use to label our products or technologies, or third parties may misuse them or create brand confusion, and our business may be negatively impacted.

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

We rely in part on trade secrets to protect our technology, and our failure to obtain or maintain trade secret protection could harm our business.

We rely on trade secrets to protect some of our technology and proprietary information, especially where we believe patent protection is not appropriate or obtainable, or may not provide effective protection. However, trade secrets are difficult to protect. It can be difficult or impossible to detect trade secret breaches. Furthermore, litigating a claim that a third party had illegally obtained and was using our trade secrets would be expensive and time consuming, and the outcome would be unpredictable. Moreover, if our competitors independently develop similar knowledge, methods and know-how, our business could be harmed.

Patent terms may be inadequate to protect our competitive position on our drug candidates for an adequate amount of time.

We have issued patents covering the composition-of-matter and the salt form of ACR-368 through 2030 and 2037, respectively, without extension, and also seek protection through our OncoSignature method-of-use patents. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case.

Patent term extensions in other countries may also be subject to certain procedural or administrative requirements including adherence to certain strict timelines. A failure to meet such requirements may result in a loss of the extension in those countries.

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

The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will have to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned patents and/or applications and any patent rights we may own or license in the future. We employ reputable law firms and other professionals to help us comply with such requirements and fee payments. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or technologies, we may not be able to stop a competitor from marketing products or technologies that are the same as or similar to our drug candidates or technologies, which would have a material adverse effect on our business. 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 non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

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

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our drug candidates and platform discovery. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material 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 management and other employees.

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

Competitors may infringe our present or future issued patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents, trademarks, copyrights or other intellectual

property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, or that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from making, using, selling, offering to sell or importing the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making, using, selling, offering to sell or importing similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that another party has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

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

Our commercial success depends, in part, upon our ability and the ability of future collaborators, if any, to develop, use, manufacture, market and sell our drug candidates and our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and technology, including interference proceedings, derivation proceedings, ex parte reexamination, post grant review and inter partes review before the USPTO or equivalent foreign regulatory authority. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future drug candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Foreign courts will have similar burdens to overcome in order to successfully challenge a third party claim of patent infringement. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our drug candidate(s) and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive,

thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or drug candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our drug candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

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 our drug candidates and technologies. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our drug candidates or our technologies, 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.

We depend on intellectual property licensed from a third party and termination of this license could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. In particular, we are dependent on our license agreement with Lilly. Any termination of this license could result in the loss of significant rights and could harm our ability to commercialize our drug candidates. See the section titled "Business—Licensing and Collaborations" for additional information.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our drug candidates and technologies infringe 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 our drug candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- our payment obligations with respect to licensed technology.

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

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we, Lilly, or any future licensors fail to adequately protect any licensed intellectual property, our ability to commercialize products could suffer.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our future drug candidates.

The United States Congress periodically enacts legislation that significantly impacts the patent system. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Various decisions by the U.S. Supreme Court and other U.S. federal courts are widely considered to have reduced patent protections available to developers of diagnostic technologies. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own or have licensed, or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents on drug candidates and technologies in all countries 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 some cases, we may not be able to obtain patent protection for certain technologies outside 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, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

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

Reliance on third parties requires us to share our proprietary information, which increases the possibility that such information will be misappropriated or disclosed.

Because we rely on third parties for aspects of development, manufacture, or commercialization of our drug candidates and technologies, or if we collaborate with third parties for the development or commercialization of our future drug candidates and technologies, we must, at times, share proprietary information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such information become known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how, a competitor's discovery of our know-how or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our know-how. Despite our efforts to protect our know-how, we may not be able to prevent the unauthorized disclosure or use of our technical know-how by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally obtained and is using our proprietary information, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect proprietary information.

Trademarks we own, license or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We rely on trademarks and expect to rely on future trademarks as one means to distinguish our drug candidates that are approved for marketing and technologies from the products of our competitors. OncoSignature is trademarked. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with ACR-368 or any future drug candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Comparable foreign regulators may have similar requirements, and it is possible that different proprietary or non-proprietary names may be required in different jurisdictions.

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

In addition to seeking patent and trademark protection for our drug candidates and technologies, we also rely on unpatented know-how, technology and other proprietary information, to maintain our competitive position. 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 unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our proprietary information. Competitors may be able to obtain or reverse engineer information about our products or technologies that would permit them to 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.

If we do not obtain patent term extension for patents covering our drug candidates, our business may be materially harmed, and in any case, the terms of our patents may not be sufficient to effectively protect our drug candidates and business.

Patents have a limited term. In most countries, including the United States, the expiration of a patent is generally 20 years after its first effective non-provisional filing date. However, depending upon the timing, duration and specifics of FDA marketing approval of ACR-368, our other drug candidates or any future drug

candidates, one or more of any U.S. patents we may be issued or have licensed may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments.

The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. 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. Patent term extension may also be available in certain foreign countries upon regulatory approval of our drug candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our competitive position, business, financial condition, results of operations, and prospects could be harmed, possibly materially.

If there are delays in obtaining regulatory approvals or other additional delays, the period of time during which we can market our drug candidates under patent protection could be further reduced. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. Once the patent term has expired, we may be open to competition from similar or generic products. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for that product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to This Offering, Ownership of our Common Stock and our Status as a Public Company

An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at or above the initial offering price, if at all.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters and may not be indicative of the price at which our common stock will trade after the closing of this offering. Although our common stock has been approved for listing on the Nasdaq Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased in this offering at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the reporting of unfavorable preclinical results;
- the commencement, enrollment or results of our clinical trials of ACR-368 or any future clinical trials we may conduct, or changes in the development status of our drug candidates;

- any delay in our regulatory filings for ACR-368 or any other drug candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our drug candidates;
- unanticipated serious safety concerns related to the use of ACR-368 or any other drug candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation or employee or independent contractor litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

The stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including recently in connection with the ongoing COVID-19 pandemic, the Russian invasion of Ukraine, rising inflation and increasing interest rates, which have resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions, may negatively affect 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 section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. 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. After this offering, we will have 18,809,823 shares of common stock outstanding based on the number of shares outstanding as of June 30, 2022. This includes the shares that we are selling in this offering, which may be resold in the public market immediately. Following the consummation of this offering, substantially all of our shares outstanding prior to this offering will be subject to a 180-day lock-up period pursuant to lock-up agreements executed in connection with this offering described in "Underwriting" and restricted from immediate resale under the federal securities laws as described in "Shares Eligible for Future Sale." All of these shares will, however, be able to be resold after the expiration of the lock-up period, as well as pursuant to customary exceptions thereto or upon the waiver of the lock-up agreement by on behalf of the underwriters. We also intend to register shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements. As restrictions on resale end, the market price of our stock could decline if the holders of currently-restricted shares sell them or are perceived by the market as intending to sell them.

We intend to file a registration statement on Form S-8 under the Securities Act to register shares subject to outstanding stock options issued under the 2019 Plan and shares of common stock reserved for issuance under the 2022 Plan and the ESPP. Both the 2022 Plan and the ESPP provide for annual automatic increases in the shares reserved for issuance under the plans which could result in additional dilution to our stockholders. Once we register the issuance of shares under these plans, they can be freely sold in the public market upon issuance, subject to the vesting of the equity awards, other restrictions provided under the terms of the applicable plan or equity award, and the lock-up period with respect to this offering.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock will be substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. To the extent outstanding options are exercised, you will incur further dilution. Based on an assumed initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $7.63 per share as of June 30, 2022, representing the difference between our pro forma as adjusted net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price.

To the extent that stock options are exercised, new equity awards are issued under our equity incentive plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common

stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Our executive officers, directors and their affiliates, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

Upon the closing of this offering, based on the number of common stock outstanding as of June 30, 2022, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates will, in the aggregate, hold common stock representing approximately 54.0% of our outstanding common stock, without giving effect to any purchases by our officers, directors and their affiliated entities in this offering. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination that other stockholders may desire. Any of these actions could adversely affect the market price of our common stock. This concentration of ownership control may:

- delay, defer, or prevent a change in control;
- entrench our management and board of directors; or
- delay or prevent a merger, consolidation, takeover, or other business combination involving us that other stockholders may desire.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own over 78.6% of our outstanding common stock prior to this offering and will continue to own a majority of our common stock following this offering. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

- an exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of this offering or, if earlier, (i) the last day of the fiscal year in which we have total annual gross revenue of at least $1.24 billion, (ii) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, or (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, we have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this prospectus may be different than the information investors may receive from other public companies in which they hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of proceeds from this offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We expect to use the net proceeds to us from this offering, together with our existing cash, cash equivalents and short-term investments, to fund the advancement of ACR-368, including CMC and companion diagnostic development, in Phase 2 clinical trials across our three lead indications into potential registrational phase, pending results and discussions with the FDA, as well as to potentially initiate Phase 2 trials in patients with HPV+ tumors, to complete IND-enabling studies for at least one of our preclinical programs and the remainder for continued development of our AP3 platform, other research and development activities, working capital and other general corporate purposes. See the section titled "Use of Proceeds." In addition, we may use a portion of the proceeds from this offering to pursue our strategy to in-license or develop additional drug candidates. Our failure to apply the net proceeds from this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

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

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner commensurate with the financial reporting requirements of an SEC registrant. Prior to the completion of this offering, we have been a private company and therefore have not designed or maintained internal controls over financial reporting commensurate with the financial reporting requirements of an SEC registrant. Accordingly, we have identified the following material weaknesses:

- We did not design and maintain an effective control environment commensurate with the financial reporting requirements of a public company. Specifically, we lacked a sufficient complement of resources with (i) an appropriate level of accounting knowledge, experience and training to appropriately analyze, record and disclose accounting matters timely and accurately as a public company, and (ii) an appropriate level of knowledge and experience to establish effective processes and controls. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently design and maintain formal accounting policies, procedures and controls or establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in our finance and accounting functions.
- We did not design and maintain effective controls in response to the risks of material misstatement. Specifically, changes to existing controls or the implementation of new controls were not sufficient to timely respond to changes to the risks of material misstatement to financial reporting due to changes in the complexity in the business.

These material weaknesses contributed to the following additional material weaknesses:

- We did not design and maintain effective controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries and the identification of and accounting for certain non-routine, unusual or complex transactions in a timely fashion, including the proper application of U.S. GAAP to such transactions. Specifically, we did not design and maintain controls to timely identify and account for preferred stock tranche rights, convertible notes and the anti-dilution right valuation.
- We did not design and maintain effective controls over information technology general controls for information systems that are relevant to the preparation of its financial statements. Specifically, we did not design and maintain: (i) program change management controls to ensure that program and data changes are identified, tested, authorized and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel; (iii) computer operations controls to ensure that processing and transfer of data, and data backups and recovery are monitored; and (iv) program development controls to ensure that new software development is tested, authorized and implemented appropriately.

None of the material weaknesses described above resulted in misstatement to our consolidated financial statements. However, the material weaknesses described above could result in a misstatement of one or more account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

Prior to the completion of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes. We are in the process of implementing measures designed to

improve our internal control over financial reporting and remediate these material weaknesses. Such measures include, but are not limited to: hiring additional finance and accounting personnel, upgrading our financial systems and implementing information technology general controls, establishing controls to identify, assess, and respond to the risks of material misstatement, and establishing controls to identify and account for certain non-routine, unusual or complex transactions in a timely fashion.

While we are currently in the process of remediating the material weaknesses, we cannot assure you that these efforts will remediate our material weaknesses in a timely manner, or at all. If we are unable to successfully remediate our material weaknesses, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, the market price of our stock may decline as a result, and we could be subject to sanctions or investigations by the Nasdaq Global Market, the SEC, or other regulatory authorities. Failure to remediate any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our restated certificate or our amended and restated bylaws;
- any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the state of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may result in increased costs for investors to bring a claim. Further, these exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds

favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

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

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

- establish a classified board of directors such that directors are elected at the annual stockholder meeting;
- allow the authorized number of our directors to be changed from time to time by our stockholders or our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish requirements for stockholder proposals that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and allow actions by our stockholders by written consent, with certain requirements;
- limit who may call stockholder meetings; and
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors.

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

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies 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 resources, which could harm our business.

General Risks

We are subject to U.S. and certain foreign anti-corruption laws and regulations, export and import controls, sanctions and embargoes. We could face liability and other serious consequences for violations.

We are subject to anti-corruption laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act and other state and national anti-bribery laws in the countries in which we may conduct activities in the future. Anti-corruption laws are interpreted broadly and generally prohibit companies and their employees, agents, contractors and other third-party collaborators from offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly through third parties, to any person in the public or private sector to obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and therefore will be considered foreign officials for purposes of the FCPA. We also expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions.

There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors or collaborators, or those of our affiliates, will comply with all applicable anti-corruption, export and import control, and sanctions laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

If we are unable to design and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

Ensuring that we have adequate internal control over financial reporting in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with this offering, we intend to begin the process of documenting, reviewing and improving our internal control over financial reporting for compliance with Section 404, which will require annual management assessment of the effectiveness of our internal control over financial reporting.

Implementing any appropriate changes to our internal control over financial reporting may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in establishing and maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. If we fail to remediate our identified material weaknesses, or identify additional material weaknesses, in our internal control over financial reporting; if we are unable to comply with the requirements of Section 404 in a timely manner; or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which could require additional financial and management resources.

We may not be able to utilize a significant portion of our net operating loss carryforwards and other tax attributes.

As of December 31, 2021, we had approximately $13.9 million federal net operating loss carryforwards and $12.3 million in state net operating loss carryforwards. The federal net operating loss carryforward can be carried forward indefinitely while the state net operating loss carryforward will begin to expire in varying amounts in 2038. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. Under the 2017 Tax Cuts and Jobs Act, or the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, federal net operating losses generated in taxable years beginning after December 31, 2017 and in future taxable years, if any, will not expire and may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 are limited to the lesser of the net operating loss carryover or 80% of the corporation's adjusted taxable income (subject to Section 382 of the Internal Revenue Code of 1986, as amended, or the Code). There is variation in how states are responding to the Tax Act and CARES Act. In addition, for state income tax purposes, there may be periods during which the use of net operating losses, or NOLs, is suspended or otherwise limited.

Separately, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by certain stockholders over a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The completion of this offering, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382 of the Code. We have not completed a Section 382 analysis, and therefore, there can be no assurances that the NOLs carryforward are not already limited.

In addition, we may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it could harm our future operating results by effectively increasing our future tax obligations.

New or future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Act, together with the CARES Act, made broad and complex changes to the U.S. tax code, including changes to U.S. federal tax rates, additional limitations on the deductibility of interest, both positive and negative changes to the utilization of future NOL carryforwards, allowing for the expensing of certain capital expenditures, and putting into effect the migration from a "worldwide" system of taxation to a territorial system.

In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have recently proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business. Recently, in the United States, Congress and the Biden administration proposed legislation (which has not yet been enacted) to make various tax law changes. These proposals, recommendations and enactments include changes to the existing framework in respect of income taxes that could apply to our business.

Unfavorable global political or 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. The global credit and financial markets have experienced severe volatility and disruptions in the past several years. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. 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. In addition, the current military conflict between Russia and Ukraine could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have been or may in the future be initiated by nations including the United States, the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, CMOs and other third parties with whom we conduct business. 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.

We will incur increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we will incur significant additional legal, accounting and other expenses that we did not incur as a private company, including the cost of director and officer liability insurance. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

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 certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of this prospectus and involve known and unknown risks, uncertainties and other important 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 the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include statements about the following:

- the timing, progress and results of our preclinical studies and clinical trials of our drug candidates, 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;
- the timing of any IND submissions, initiation of clinical trials and timing of expected clinical results for ACR-368 and our other future drug candidates;
- the timing of any submission of filings for regulatory approval of, and our ability to obtain and maintain regulatory approvals for, ACR-368 and any other drug candidates for any indication;
- the ongoing COVID-19 pandemic, including new variants of the virus, which could adversely impact our business, including our preclinical studies and clinical trials;
- our ability to identify patients with the cancers treated by our drug candidates, and to enroll patients in trials;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our drug candidates, if approved for commercial use;
- our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes;
- our expectations regarding the scope of any approved indication for ACR-368 or any other drug candidate;
- our ability to successfully commercialize our drug candidates;
- our ability to leverage our AP3 platform to identify and develop future drug candidates;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for or ability to obtain additional funding before we can expect to generate any revenue from drug sales;
- our ability to establish or maintain collaborations or strategic relationships;
- our ability to identify, recruit and retain key personnel;
- our reliance upon intellectual property licensed from third parties and our ability to obtain such licenses on commercially reasonable terms or at all;
- our ability to protect and enforce our intellectual property position for our drug candidates, and the scope of such protection;

- our financial performance;
- our expected use of proceeds from this offering;
- our competitive position and the development of and projections relating to our competitors or our industry;
- our estimates regarding future revenue, expenses and needs for additional financing;
- the impact of laws and regulations; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

The foregoing list of risks is not exhaustive. Other sections of this prospectus may include additional factors that could harm our business and financial 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. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, the events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the “Risk Factors” section of this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

MARKET AND INDUSTRY DATA

We obtained the industry, statistical and market data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. All of the market data used in this prospectus involve a number of assumptions and limitations, and the sources of such data cannot guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 5,900,000 shares of our common stock in this offering will be approximately $90.4 million (or approximately $104.4 million if the underwriters exercise in full their option to purchase up to 885,000 additional shares), assuming an initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $17.00 per share would increase (decrease) the net proceeds to us from this offering by approximately $5.5 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $15.8 million, assuming the assumed initial public offering price stays the same.

We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, as follows:

- approximately $80.0 million to $90.0 million to fund the advancement of ACR-368, including CMC and companion diagnostic development, in Phase 2 clinical trials across our three lead indications into potential registrational phase, pending the results and discussions with the FDA, as well as to potentially initiate Phase 2 trials in patients with HPV+ tumors;
- approximately $15.0 million to $20.0 million to complete IND-enabling studies for at least one of our preclinical programs; and
- the remainder for continued development of our AP3 platform, other research and development activities, working capital and other general corporate purposes.

As of June 30, 2022, we had cash and cash equivalents of $83.9 million. Based on our current operational plans and assumptions, we expect our cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements at least into the fourth quarter of 2024. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents as of June 30, 2022, will be insufficient to fund any of our drug candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize our drug candidates. It is difficult to predict the cost and timing required to complete development and obtain regulatory approval of, and commercialize, our drug candidates due to, among other factors, our limited experience with initiating, conducting and completing clinical trials, obtaining regulatory approval and commercializing our drug candidates, the rate of subject enrollment in our clinical trials, filing requirements with various regulatory agencies, clinical trial results and the actual costs of manufacturing and supplying our drug candidates.

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. We believe that opportunities may exist from time to time to expand our current business through licenses with or acquisitions of, or investments in, complementary businesses, products or technologies, and we may use a portion of the net proceeds for these purposes.

Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing, cost and success of preclinical studies and clinical trials, the timing of

regulatory submissions, our ability to obtain additional financing, the amount of cash obtained through our existing collaborations and future collaborations, if any, and any unforeseen cash needs.

Pending any use described above, we intend to invest the net proceeds of this offering in short- and intermediate-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid, and do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, and our capitalization as of June 30, 2022:

- on an actual basis;
- on a pro forma basis to give effect to: (1) the conversion of all outstanding shares of our preferred stock into an aggregate of 11,140,262 shares of our common stock upon the closing of this offering; and (2) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give effect to: (1) the pro forma adjustments described above; and (2) our issuance and sale of 5,900,000 shares of common stock in this offering at an assumed initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing at the end of this prospectus, the sections of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information contained in this prospectus.

	As of June 30, 2022		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 83,861	$ 83,861	$ 174,251
Convertible preferred stock, $0.001 par value per share; 27,471,911 shares authorized; 27,471,911 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	$122,518	$ —	$ —
Stockholders' (deficit) equity:			
Preferred stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value per share; 40,013,683 shares authorized, 1,769,561 shares issued and outstanding, actual; 500,000,000 shares authorized, 12,909,823 shares issued and outstanding, pro forma; 500,000,000 authorized, 18,809,823 issued and outstanding, pro forma as adjusted	2	13	19
Additional paid-in capital	1,327	123,834	214,207
Accumulated deficit	(37,905)	(37,905)	(37,905)
Total stockholders' (deficit) equity	(36,576)	85,942	176,321
Total capitalization	$ 85,942	$ 85,942	$ 176,321

Each $1.00 increase (decrease) in the assumed initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, additional paid in capital, total stockholders' equity (deficit) and total capitalization by approximately $5.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase

(decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price per share of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, additional paid in capital, total stockholders' equity (deficit) and total capitalization by approximately $15.8 million.

The number of shares of our common stock to be outstanding after this offering is based on 12,909,823 shares of our common stock outstanding as of June 30, 2022, after giving effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 11,140,262 shares of common stock, and excludes:

- 2,072,851 shares of our common stock issuable upon the exercise of options outstanding as of June 30, 2022 under the 2019 Plan, at a weighted-average exercise price of $2.85 per share (of which (i) options to purchase an aggregate of 25,039 shares of common stock were exercised subsequent to June 30, 2022 and (ii) options to purchase an aggregate of 65,392 shares of common stock were canceled subsequent to June 30, 2022), which does not include options to purchase an aggregate of 166,259 shares of our common stock, at a weighted-average exercise price of $4.07 per share, that were granted subsequent to June 30, 2022;
- 1,003,666 shares of our common stock available for future issuance as of June 30, 2022 under the 2019 Plan, which shares will cease to be available for issuance under the 2019 Plan at the time the 2022 Plan becomes effective and will be added to, and become available for issuance under, the 2022 Plan;
- an additional 2,555,571 shares of our common stock reserved for future issuance under the 2022 Plan, which will become effective on the date of the underwriting agreement related to this offering (of which we will grant certain options to purchase shares of common stock at an exercise price equal to the initial public offering price and certain restricted stock units, as described in "Executive Compensation"), as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2022 Plan and any additional shares of our common stock that may become available under our 2022 Plan, as more fully described in "Executive Compensation—Equity Incentive Plans"; and
- 215,000 shares of our common stock reserved for future issuance under the ESPP, which will become effective on the date of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

DILUTION

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

As of June 30, 2022, we had a historical net tangible book deficit of $36.8 million, or $20.80 per share of our common stock. Our historical net tangible book deficit per share represents total tangible assets less total liabilities and the carrying values of our convertible preferred stock, which is not included within stockholders' deficit divided by the 1,769,561 shares of our common stock outstanding as of June 30, 2022.

Our pro forma net tangible book value as of June 30, 2022 was $85.7 million, or $6.64 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 conversion of all outstanding shares of our preferred stock into an aggregate of 11,140,262 shares of our common stock, as if such conversion had occurred upon the closing of this offering. 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, 2022, after giving effect to the pro forma adjustment described above.

After giving further effect to the sale of 5,900,000 shares of common stock in this offering at an assumed initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2022 would have been $176.3 million, or $9.37 per share. This amount represents an immediate increase in pro forma net tangible book value of $2.73 per share to our existing stockholders and immediate dilution of $7.63 per share to new investors in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$17.00
Historical net tangible book deficit per share as of June 30, 2022	$(20.80)	
Pro forma increase in historical net tangible book value per share attributable to the pro forma transactions described in the preceding paragraphs	27.44	
Pro forma net tangible book value per share as of June 30, 2022	6.64	
Increase in pro forma net tangible book value per share attributable to this offering	2.73	
Pro forma as adjusted net tangible book value per share after this offering		9.37
Dilution per share to new investors in this offering		$ 7.63

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase (decrease) in the assumed initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately $0.29, and dilution in pro forma net tangible book value per share to new investors by approximately $0.71, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1.0 million shares in the number of shares we are offering would increase the pro forma as adjusted net tangible book value per share after this offering by $0.33 and decrease the dilution per share to new investors participating in this offering by $0.33, assuming no change in the assumed initial public offering price per share and after deducting the estimated

underwriting discounts and commissions. A decrease of 1.0 million shares in the number of shares we are offering would decrease the pro forma as adjusted net tangible book value per share after this offering by $0.36 and increase the dilution per share to new investors participating in this offering by $0.36, assuming no change in the assumed initial public offering price per share and after deducting the estimated underwriting discounts and commissions.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after this offering would be $9.66 per share, the increase in pro forma net tangible book value per share would be $3.02 and the dilution per share to new investors would be $7.34 per share, in each case assuming an initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, as of June 30, 2022, on the pro forma as adjusted basis described above, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share that existing stockholders and new investors paid for such shares. The calculation below is based on an assumed initial public offering price of $17.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price per Share
	Number	Percent	Amount	Percent	
Existing stockholders	12,909,823	68.6%	$120,252,566	54.5%	$ 9.31
New investors	5,900,000	31.4	100,300,000	45.5	$ 17.00
Total	18,809,823	100%	$220,552,566	100%	

The number of shares of our common stock to be outstanding after this offering is based on 12,909,823 of shares of our common stock outstanding as of June 30, 2022, after giving effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 11,140,262 shares of common stock, and excludes:

- 2,072,851 shares of our common stock issuable upon the exercise of options outstanding as of June 30, 2022 under the 2019 Plan, at a weighted-average exercise price of $2.85 per share (of which (i) options to purchase an aggregate of 25,039 shares of common stock were exercised subsequent to June 30, 2022 and (ii) options to purchase an aggregate of 65,392 shares of common stock were canceled subsequent to June 30, 2022), which does not include options to purchase an aggregate of 166,259 shares of our common stock, at a weighted-average exercise price of $4.07 per share, that were granted subsequent to June 30, 2022;
- 1,003,666 shares of our common stock available for future issuance as of June 30, 2022 under the 2019 Plan, which shares will cease to be available for issuance under the 2019 Plan at the time the 2022 Plan becomes effective and will be added to, and become available for issuance under, the 2022 Plan;
- an additional 2,555,571 shares of our common stock reserved for future issuance under the 2022 Plan, which will become effective on the date of the underwriting agreement related to this offering (of which we will grant certain options to purchase shares of common stock at an exercise price equal to the initial public offering price and certain restricted stock units, as described in “Executive Compensation”), as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2022 Plan and any additional shares of our common stock that may become available under our 2022 Plan, as more fully described in “Executive Compensation—Equity Incentive Plans”; and
- 215,000 shares of our common stock reserved for future issuance under the ESPP, which will become effective on the date of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

To the extent that stock options are exercised, new equity awards are issued under our equity incentive plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could 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 consolidated financial statements and related notes and other financial information 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 and strategy 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 "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical stage biopharmaceutical company developing precision oncology medicines that we match to patients whose tumors are predicted to be sensitive to each specific medicine by utilizing our proprietary proteomics-based patient responder identification platform. Recently approved targeted oncology treatments, such as kinase inhibitors, have transformed the cancer treatment landscape, and while the therapeutic benefit of these agents has provided significant benefit to patients, these targeted oncology treatments unfortunately only address the less than 10% of patients with cancers that harbor certain easily-identifiable genetic mutations. Our approach is designed to overcome the limitations of genomics-based patient selection methods. We do this by using our proprietary precision medicine platform, AP3, to develop our pipeline of oncology drug candidates. Our AP3 platform enables the creation of drug-specific proprietary OncoSignature companion diagnostics that are used to identify the patients most likely to benefit from our drug candidates, which we refer to as patient responders. We are currently advancing our lead candidate, ACR-368, a selective small molecule inhibitor targeting CHK1 and CHK2 with sub single-digit nM and single-digit nM potency, respectively, in a potentially registrational Phase 2 trial across multiple tumor types, which our AP3 platform predicts will have a high proportion of patient responders based on OncoSignature-predicted sensitivity to ACR-368. Our ACR-368 OncoSignature test, which has not yet obtained regulatory approval, has been extensively evaluated in preclinical studies, including in two separate, blinded, prospectively-designed studies on pretreatment tumor biopsies collected from patients with ovarian cancer treated with ACR-368 in past Phase 2 clinical trials conducted by Eli Lilly and Company, or Lilly, and at the National Cancer Institute demonstrating robust enrichment of responders through our method.

Since our inception in 2018, we have devoted substantially all of our resources toward conducting discovery and research activities, organizing and staffing our company, business planning, acquiring or discovering drug candidates, establishing and protecting our intellectual property portfolio, developing and progressing ACR-368 and the ACR-368 OncoSignature, preparing for and conducting preclinical studies and clinical trials, establishing arrangements with third parties for the manufacture of ACR-368, the ACR-368 Oncosignature and component materials, as well as raising capital. We do not have any drug candidates approved for sale and have not generated any revenue from drug sales. Since inception, we have funded our operations primarily through equity and convertible debt financings and have received aggregate net proceeds of $119.8 million from the issuance of convertible notes and the sale of our Series A-1 convertible preferred stock, or Series A-1 Preferred Stock, and Series B convertible preferred stock, or Series B Preferred Stock, which we refer to collectively as our Preferred Stock.

We have incurred operating losses since inception. Our net losses for the six months ended June 30, 2022 and 2021 were $13.0 million and $9.5 million, respectively. Our net losses for the years ended December 31, 2021 and 2020 were $16.2 million and $5.3 million, respectively. As of June 30, 2022, we had an accumulated deficit of $37.9 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, particularly if and as we:

- continue to conduct preclinical studies and clinical trials for ACR-368;

- initiate and conduct additional preclinical studies and clinical trials for ACR-368;
- continue to discover and develop additional drug candidates and the ACR-368 OncoSignature tests;
- acquire or in-license other drug candidates and technologies;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional clinical and scientific personnel;
- further develop and refine the manufacturing processes for ACR-368, the ACR-368 OncoSignature or any future drug candidates;
- seek regulatory approvals and pursue commercialization for any drug candidates that successfully complete clinical trials; and
- add operational, financial, and management information systems and personnel, including personnel to support our drug development and planned future commercialization efforts, as well as to support our transition to a public reporting company.

Following the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company. Furthermore, we will not generate revenue from drug sales until we successfully complete clinical development and obtain regulatory approval for a drug candidate. In addition, if we obtain regulatory approval for a drug candidate and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support drug sales, marketing, manufacturing and distribution activities. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical studies and our expenditures on other research and development activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time that we can generate significant revenue from drug sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. If we are unable to raise capital as needed, this could have a negative impact on our financial condition and ability to pursue our business strategies including requiring us to delay, reduce or eliminate drug development or future commercialization efforts. The amount and timing of our future funding requirements will depend on many factors including the successful advancement of ACR-368, the ACR-368 OncoSignature, or any future drug candidates. Our ability to raise additional funds may also be adversely impacted by potential worsening global economic conditions, and disruptions to, and volatility in the credit and financial markets in the United States and worldwide, such as those resulting from the ongoing COVID-19 pandemic and the hostilities in Ukraine. There can be no assurances that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

As of June 30, 2022, we had cash and cash equivalents of $83.9 million. We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents as of June 30, 2022, will enable us to fund our operating expenses and capital expenditure requirements at least into the fourth quarter of 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 the section titled "—Liquidity and Capital Resources."

License Agreement with Eli Lilly and Company

In January 2021, we entered into a license agreement and stock issuance agreement, or, collectively, the Lilly Agreement, with Lilly, pursuant to which we have been granted an exclusive, royalty-bearing sublicensable license to certain intellectual property rights owned or controlled by Lilly, to commercially develop, manufacture, use, distribute and sell therapeutic products containing the compound prexasertib.

Under the terms of the agreement, we paid Lilly an initial upfront fee payment of $5.0 million. In connection with entering into the agreement, we also entered into a common stock issuance agreement with Lilly pursuant to which we issued Lilly 336,575 shares of our common stock and 46,058 shares of Series B Preferred Stock, which will convert into 18,677 shares of common stock immediately upon the closing of this offering. As additional consideration for the license, we are required to pay Lilly aggregate development and commercial milestone payments of up to $168.0 million, of which $5.0 million is due prior to NDA. No development or commercial milestones have been achieved to date under the Lilly Agreement. We are also obligated to pay a tiered percentage royalty on annual net sales ranging from a low single-digit up to a maximum of 10%, subject to certain specified reductions. Royalties are payable by us on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last valid claim covering the licensed product in such country, expiration of all applicable regulatory exclusivities in such country for such licensed product and the tenth anniversary of the first commercial sale of such licensed product in such country, provided, that our obligation to pay royalties for a given licensed product in a given country will expire earlier upon achievement of certain sales thresholds by generic products in such country.

For a more detailed description of this agreement, see the section titled "Business—Licensing and Collaborations" and Note 7 to our consolidated financial statements included elsewhere in this prospectus.

Companion Diagnostic Agreement

In June 2022, we entered into a companion diagnostic agreement with Akoya Biosciences, Inc., or Akoya, pursuant to which we agreed to co-develop, validate, and commercialize our proprietary ACR-368 OncoSignature test, the companion diagnostic that will be used to identify patients with cancer most likely to respond to ACR-368.

Pursuant to the agreement, we paid Akoya a one-time, non-refundable, non-creditable upfront payment in the amount of $0.6 million. We are obligated to pay Akoya up to an aggregate of $10.3 million upon the achievement of specified development milestones. As of October 17, 2022, development milestones have been achieved under the agreement, resulting in payments of $2.3 million by us to Akoya. Other than certain specified pass-through costs, each party is responsible for its own costs associated with the development of the companion diagnostic. Akoya will procure and manufacture necessary supplies to perform the ACR-368 OncoSignature test to support our clinical development and commercial requirements, in accordance with a supply agreement to be mutually agreed upon by the parties. We may terminate the agreement at our convenience, subject to the payment of a termination fee in the amount of $1.0 million.

For a more detailed description of this agreement, see the sections titled "Business—Licensing and Collaborations" and "—Contractual Obligations."

Impact of COVID-19 on Our Business

The extent of the impact of the novel coronavirus, or COVID-19, pandemic on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our CMOs, CROs, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. While we continue to conduct our research and development activities, the COVID-19 pandemic may cause disruptions that impact the timing of our preclinical studies and clinical trials of ACR-368 and affect our ability to complete preclinical studies, future clinical trials or to procure items that are essential for our research and development activities. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of the pandemic. To date, there has not been a significant impact on the development of ACR-368 and the ACR-368 OncoSignature or the rest of our pipeline; however, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic could potentially have on our ongoing business plan, financial condition and operations.

Components of Results of Operations

Revenue

To date, we have not generated any revenue, and we do not expect to generate any revenue in the foreseeable future from drug sales. We may in the future generate revenue from payments received under collaboration agreements, which includes payments of upfront fees, license fees, milestone-based payments and reimbursements for research and development efforts.

Operating Expenses

Research and Development

The majority of our expenses has been research and development expenses, which consist primarily of costs incurred in connection with our research and development activities, including our drug discovery efforts and the development of ACR-368 and the ACR-368 OncoSignature. We expense research and development costs as incurred, which include:

- direct cost for conducting internal research and development to generate preclinical validation data for ACR-368 including the ACR-368 OncoSignature, and for our internal preclinical drug discovery programs;
- the cost to obtain and maintain licenses to intellectual property, such as those with Lilly and related future payments should certain milestones be achieved;
- external research and development expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our clinical trials and other scientific development services;
- costs related to manufacturing material for our clinical trials, including fees paid to CMOs;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing clinical trial materials;
- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation and other related costs for those employees involved in research and development efforts;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- expenses to acquire technologies, such as intellectual property, to be used in research and development;
- upfront and maintenance fees incurred under license, acquisition and other third-party agreements;
- costs related to regulatory activities, including filing fees paid to regulatory agencies and compliance with regulatory requirements; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent, maintenance of facilities and equipment and software.

Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our discovery studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

We characterize research and development costs incurred prior to the identification of a drug candidate as discovery costs. Once a drug candidate has been identified, research and development costs incurred are allocated as drug candidate costs.

Our direct, internal research and development costs consist primarily of costs for reagents and material supplies for our ACR-368 OncoSignature test and for cellular and human tissue samples and reagents necessary for our preclinical drug discovery programs.

Our external research and development expenses consist primarily of fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our process development, manufacturing, and clinical development activities. Our direct external research and development expenses also include fees incurred under license and intellectual property purchase agreements. We track these external research and development costs on a program-by-program basis once we have identified a drug candidate.

A significant portion of our research and development costs to date have been third-party costs, which we track on an individual drug candidate basis after a clinical drug candidate has been identified. Currently, our sole clinical drug candidate is ACR-368.

Our indirect research and development costs are primarily personnel-related costs, facilities, which is offset by a portion of our allocable sublease rent income, and other costs. Employees and infrastructure are not directly tied to any one program and are deployed across our programs. As such, we do not track these costs on a specific program basis.

We do not allocate employee costs associated with our discovery efforts, or facility costs, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources and third-party consultants primarily to conduct our research and discovery activities as well as for managing our process development, manufacturing and clinical development activities.

The successful development of our ACR-368 and ACR-368 OncoSignature test or any other future drug candidates is highly uncertain. We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of ACR-368 and manufacturing processes and conduct discovery and research activities for our clinical programs.

We cannot determine with certainty the timing of initiation, the duration, or the completion costs of current or future clinical trials of our drug candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which drug candidates to pursue and how much funding to direct to each drug candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments and our ongoing assessments as to each drug candidate's commercial potential. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase significantly with our ongoing clinical trials. We anticipate that our expenses will increase substantially, particularly due to the numerous risks and uncertainties associated with developing drug candidates, including the uncertainty of:

- the scope, rate of progress and expenses of our ongoing research activities and clinical trials and other research and development activities;
- confirming the appropriate safety profile established in past clinical trials;
- successful enrollment in and completion of clinical trials;
- whether our drug candidates show efficacy with an increased objective response rate through patient responder identification in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates;
- the extent to which we establish additional collaboration or license agreements;

- commercializing drug candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

Any changes in the outcome of any of these variables with respect to the development of our drug candidates in clinical development could mean a significant change in the costs and timing associated with the development of these drug candidates. We may never succeed in achieving regulatory approval for any of our drug candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some drug candidates or focus on others. For example, if the U.S. Food and Drug Administration, European Medicines Agency or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that drug candidate.

General and Administrative

General and administrative expenses consist primarily of employee-related costs, including salaries, bonuses, benefits, and stock-based compensation expenses for personnel in executive, finance, accounting, human resources and other administrative functions. Other significant general and administrative expenses include legal fees relating to patent, intellectual property and corporate matters, fees paid for accounting, audit, consulting and other professional services, and expenses for rent, insurance and other operating costs. An allocated portion of sublease rent income is recorded as an offset to general and administrative expense.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our drug candidates. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Total Other Income (Expense), Net

Other Income

Other income primarily consists of interest income, which is earned on cash equivalents that generate interest on a monthly basis.

Change in Fair Value of Convertible Notes

The convertible notes, or the Notes, were related to our obligation to issue shares of Preferred Stock to investors, which were converted into Series A-1 Preferred Stock in October 2020. We elected the fair value option to account for the Notes. The Notes were classified as a liability on our consolidated balance sheets and initially recorded at fair value. The Notes were subsequently revalued with changes in fair value for each reporting period recognized in other income (expense), net until converted.

Change in Fair Value of Preferred Stock Tranche Rights

The preferred stock tranche rights, or Preferred Stock Tranche Rights, were related to our obligation to issue shares of Series A-1 Preferred Stock in subsequent second and third closings upon the occurrence of one of four milestones. This obligation was fully satisfied in January 2021 when the third and final tranche of the Series A-1 Preferred Stock was closed. The Preferred Stock Tranche Rights were classified as a liability on our consolidated balance sheets and initially recorded at fair value. The Preferred Stock Tranche Rights were subsequently

revalued until the tranches were settled, with changes in fair value for each reporting period recognized in other income (expense), net. Upon the issuance of the Preferred Stock Tranche Right shares, the fair value of the related Preferred Stock Tranche Rights was reclassified to Series A-1 Preferred Stock.

Change in Fair Value of Anti-dilution Right

The anti-dilution right, or Anti-dilution Right, related to our obligation to issue capital stock to Lilly for no consideration upon a future financing. We determined that the Anti-dilution Right was a freestanding financial instrument, and it was classified as a liability on our consolidated balance sheets and initially recorded at fair value. We determined that the Lilly Agreement represented an asset acquisition of in process research and development, or IPR&D, assets with no alternative future use and recognized the aggregate acquisition cost as acquired IPR&D expense in the consolidated statements of operations and comprehensive loss. The Anti-dilution Right was subsequently revalued until anti-dilution shares were issued and the Anti-dilution Right was settled, with changes in fair value for each reporting period recognized in other income (expense), net. Upon issuance of the anti-dilution shares in November 2021, the fair value of the Anti-dilution Right was reclassified to Series B Preferred Stock.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each year and interim period, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

As of December 31, 2021, we had $13.9 million and $12.3 million of federal and state operating loss carryforwards, respectively. The federal NOLs are not subject to expiration and the state NOLs begin to expire in 2038. These loss carryforwards are available to reduce future federal taxable income, if any.

Results of Operations

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations (in thousands):

	Six Months Ended June 30,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 10,145	$ 8,448	$ 1,697
General and administrative	2,992	795	2,197
Total operating expenses	13,137	9,243	3,894
Loss from operations	(13,137)	(9,243)	(3,894)
Other income (expense):			
Other income, net	97	41	56
Change in fair value of preferred stock tranche rights	—	(50)	50
Change in fair value of anti-dilution right	—	(208)	208
Total other income (expense), net	97	(217)	314
Net loss	$ (13,040)	$ (9,460)	$(3,580)

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Six Months Ended June 30,		
	2022	2021	Change
Direct research and development expenses by program:			
ACR-368	$ 4,101	$ 5,758	$(1,657)
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	2,950	871	2,079
Other drug discovery programs	2,529	1,260	1,269
Facilities, supplies and other	565	559	6
Total research and development expenses	$ 10,145	$ 8,448	$ 1,697

Research and development expenses were $10.1 million for the six months ended June 30, 2022, compared to $8.4 million for the six months ended June 30, 2021. The increase of $1.7 million was primarily due to:

- a $1.7 million decrease in costs related to the development of ACR-368, primarily due to a $5.5 million decrease from the upfront fees associated with the Lilly Agreement in the prior year, offset by increased costs of $3.8 million related to the development of ACR-368, which included $2.0 million from increased activity in the outsourcing of manufacturing and the development of clinical trials, and an increase of $1.8 million in costs related to the onboarding of CROs in clinical trials;
- a $2.1 million increase in personnel-related costs, including $0.5 million of recruiting expense and $0.1 million of stock-based compensation expense, primarily due to an increase in headcount in support of research activities; and
- a $1.3 million increase in costs related to discovery activities as a result of increased efforts toward identifying drug candidates.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands):

	Six Months Ended June 30,		
	2022	2021	Change
Personnel related (including stock-based compensation)	$ 1,724	$ 313	$1,411
Legal and professional fees	939	174	765
Facilities, supplies and other	329	308	21
Total general and administrative expenses	$ 2,992	$ 795	$2,197

General and administrative expenses were $3.0 million for the six months ended June 30, 2022, compared to $0.8 million for the six months ended June 30, 2021. The increase of $2.2 million was primarily due to:

- a $1.4 million increase in payroll and personnel-related costs, primarily due to an increase in headcount, including the hiring of our chief financial officer; and
- a $0.8 million increase in legal, accounting and professional fees, primarily due to preparation for our initial public offering, or IPO.

Total Other Income (Expense), Net

Total other income, net was $0.1 million for the six months ended June 30, 2022, compared to total other expense, net of $0.2 million for the six months ended June 30, 2021. The change of $0.3 million is primarily

attributable to a $0.2 million loss attributable to the change in the fair value of the Anti-dilution Right upon remeasurement as of June 30, 2021 prior to settlement in November 2021, a $0.1 million loss attributable to the change in the fair value of the Preferred Stock Tranche Rights upon remeasurement immediately prior to settlement in January 2021, and an increase of $0.1 million in other income, net primarily related to an increase in interest income on our cash equivalents.

Comparison of the Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 13,718	$ 1,870	$ 11,848
General and administrative	2,466	1,298	1,168
Total operating expenses	16,184	3,168	13,016
Loss from operations	(16,184)	(3,168)	(13,016)
Other income (expense):			
Other income, net	21	32	(11)
Change in fair value of convertible notes	—	(2,099)	2,099
Change in fair value of preferred stock tranche rights	(50)	(71)	21
Change in fair value of anti-dilution right	(30)	—	(30)
Total other expense, net	(59)	(2,138)	2,079
Net loss and comprehensive loss	$ (16,243)	$ (5,306)	$(10,937)

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Direct research and development expenses by program:			
ACR-368	$ 7,896	$ 556	$ 7,340
Unallocated research and development expenses:			
Other drug discovery programs	2,876	577	2,299
Personnel related (including stock-based compensation)	1,965	485	1,480
Facilities, supplies and other	981	252	729
Total research and development expenses	$ 13,718	$ 1,870	$11,848

Research and development expenses were $13.7 million for the year ended December 31, 2021, compared to $1.9 million for the year ended December 31, 2020. The increase of $11.8 million was primarily due to:

- a $7.3 million increase in costs related to the development of ACR-368, primarily due to costs associated with the Lilly Agreement, including the upfront payment to Lilly of $5.0 million, the initial fair value of the Anti-dilution Right of $0.2 million, and the issuance of common stock to Lilly of $0.3 million, an increase of $1.1 million due to the increased activity in outsourcing of manufacturing and the development of clinical trials, and an increase of $0.7 million due to increased costs related to the onboarding of CROs in clinical trials;
- a $2.3 million increase in costs related to discovery activities as a result of increased efforts toward identifying drug candidates;

- a $1.5 million increase in personnel-related costs, including $0.4 million of stock-based compensation expense, primarily due to an increase in headcount in support of research activities; and
- a $0.7 million increase in facilities, supplies and other expenses, primarily due to a $1.0 million increase in facilities, rent, travel and equipment driven by an increase in headcount in support of research activities, offset by a $0.3 million increase in allocated sublease rent income, which is recorded as an offset to research and development expenses.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Personnel related (including stock-based compensation)	$ 1,366	$ 711	$ 655
Legal and professional fees	613	385	228
Facilities, supplies and other	487	202	285
Total general and administrative expenses	$ 2,466	$ 1,298	$1,168

General and administrative expenses were $2.5 million for the year ended December 31, 2021, compared to $1.3 million for the year ended December 31, 2020. The increase of $1.2 million was primarily due to:

- a $0.7 million increase in payroll and personnel-related costs, including $0.1 million of stock-based compensation, primarily due to an increase in headcount;
- a $0.2 million increase in legal, accounting and professional fees; and
- a $0.3 million increase in facilities, supplies, and other expenses, primarily due to a $0.4 million increase in facilities, rent, travel and equipment driven by an increase in headcount, offset by a $0.1 million increase in allocated sublease rent income, which is recorded as an offset to general and administrative expenses.

Total Other Expense, Net

Total other expense, net was $0.1 million for the year ended December 31, 2021, compared to total other expense, net of $2.1 million for the year ended December 31, 2020. The decrease of $2.0 million is primarily attributable to a $2.1 million loss attributable to the change in the fair value of the Notes upon remeasurement in October 2020, prior to conversion.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not recognized any revenue and have incurred significant losses in each period and on an aggregate basis. We have not yet commercialized any drug candidates, and we do not expect to generate revenue from sales of any drug candidates or from other sources for several years, if at all. As of June 30, 2022, we had $83.9 million in cash and cash equivalents, and we had an accumulated deficit of $37.9 million. We have funded our operations primarily with net proceeds of $119.8 million from the issuance of convertible notes and sales of our Preferred Stock.

Cash Flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Six Months Ended June 30,		Year Ended December 31,	
	2022	2021	2021	2020
Net cash used in operating activities	$ (14,242)	$ (8,041)	$ (13,982)	$ (2,803)
Net cash used in investing activities	(1,489)	(101)	(238)	(15)
Net cash (used in) provided by financing activities	(11)	12,467	112,221	2,889
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (15,742)	$ 4,325	$ 98,001	$ 71

Net Cash Used in Operating Activities

Net cash used in operating activities was $14.2 million for the six months ended June 30, 2022, reflecting a net loss of $13.0 million and a net change of $2.0 million in our net operating assets and liabilities, partially offset by non-cash charges of $0.8 million. Non-cash charges primarily consisted of non-cash lease expense of $0.4 million, stock-based compensation expense of $0.3 million, and depreciation of $0.1 million. The change in our net operating assets and liabilities was primarily due to a $2.5 million increase in prepaid expenses and other current assets and a $0.3 million decrease in operating lease liabilities, partially offset by a $0.4 million increase in accounts payable and a $0.4 million increase in accrued expenses and other liabilities. The increase in prepaid expenses and other current assets was primarily due to the timing of payments to vendors, the decrease in operating lease liabilities was due to lease payments on our leases, the increase in accounts payable and accrued expenses and other liabilities was primarily due to an increase in research and development costs and an increase in headcount.

Net cash used in operating activities was $8.0 million for the six months ended June 30, 2021, reflecting a net loss of $9.5 million, partially offset by non-cash charges of $1.3 million and a net change of $0.1 million in our net operating assets and liabilities. Non-cash charges primarily consisted of non-cash lease expense of $0.3 million, the cost of the Lilly Agreement paid for in common stock of $0.3 million, stock-based compensation expense of $0.2 million, the cost of the Anti-dilution Right assumed with the Lilly Agreement of $0.2 million, and the change in the fair value of the Anti-dilution right of $0.2 million. The change in our net operating assets and liabilities was primarily due to a $0.2 million increase in accrued expenses and other liabilities and a $0.1 million increase in accounts payable, partially offset by a $0.2 million decrease in operating lease liabilities. The increase in accounts payable and accrued expenses and other liabilities was primarily due to an increase in research and development costs and an increase in headcount, and the decrease in operating lease liabilities was due to lease payments on our leases.

Net cash used in operating activities was $14.0 million for the year ended December 31, 2021, reflecting a net loss of $16.2 million, partially offset by non-cash charges of $1.9 million and a net change of $0.3 million in our net operating assets and liabilities. Non-cash charges primarily consisted of non-cash lease expense of $0.8 million, stock-based compensation expense of $0.5 million, the cost of the Lilly Agreement paid for in common stock of $0.3 million, and the cost of the Anti-dilution Right assumed with the license agreement of $0.2 million. The change in our net operating assets and liabilities was primarily due to a $0.9 million increase in accrued expenses and other liabilities and a $0.8 million increase in accounts payable, partially offset by a $0.8 million increase in prepaid expenses and other current assets and a $0.6 million decrease in operating lease liabilities. The increase in accounts payable was primarily due to an increase in research and development costs, the increase in accrued expenses and other liabilities was primarily due to an increase in research and development costs and an increase in headcount, the increase in prepaid expenses and other current assets was primarily due to the timing of payments to vendors, and the decrease in operating lease liabilities was due to lease payments on our leases.

Net cash used in operating activities was $2.8 million for the year ended December 31, 2020, reflecting a net loss of $5.3 million, partially offset by non-cash charges of $2.2 million and a net change of $0.3 million in our net operating assets and liabilities. Non-cash charges primarily consist of a change in fair value of the Notes of $2.1 million and the change in the fair value of Preferred Stock Tranche Rights of $0.1 million. The change in our net operating assets and liabilities was primarily due to a $0.4 million increase in accrued expenses and other liabilities and a $0.1 million increase in accounts payable, partially offset by a $0.1 million increase in prepaid expenses and other current assets. The increase in accrued expenses and other liabilities was primarily due to an increase in research and development costs and an increase in headcount.

Net Cash Used in Investing Activities

Net cash used in investing activities was $1.5 million and $0.1 million for the six months ended June 30, 2022 and 2021, respectively, and resulted from our purchases of property and equipment, consisting largely of laboratory equipment purchases to support our expanded headcount and continued research and development activities.

Net cash used in investing activities was $0.2 million and $15,000 for the year ended December 31, 2021 and 2020, respectively, and resulted from our purchases of property and equipment.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $11,000 for the six months ended June 30, 2022, resulting from the payment of deferred offering costs.

Net cash provided by financing activities was $12.5 million for the six months ended June 30, 2021, resulting from proceeds received from the issuance and sale of shares of our Series A-1 Preferred Stock, net of issuance costs.

Net cash provided by financing activities was $112.2 million for the year ended December 31, 2021, resulting from proceeds received from the issuance and sale of shares of our Series A-1 Preferred Stock, net of issuance costs, of $12.5 million and from the issuance and sale of our Series B Preferred Stock, net of issuance costs, of $99.8 million.

Net cash provided by financing activities was $2.9 million for the year ended December 31, 2020, resulting from proceeds received from the issuance and sale of shares of our Series A-1 Preferred Stock, net of issuance costs of $2.8 million and proceeds from the issuance of our payment protection program loan of $0.1 million.

Funding Requirements

As of June 30, 2022, our cash and cash equivalents were $83.9 million. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents as of June 30, 2022, will enable us to fund our operating expenses and capital expenditure requirements at least into the fourth quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates through clinical development, seek regulatory approval and pursue commercialization of any approved drug candidates. We expect that our research and development and general and administrative costs will increase in connection with our planned research and clinical activities. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. If we receive regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses

related to drug manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We may also require additional capital to pursue in-licenses or acquisitions of other drug candidates.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drug candidates, we are unable to accurately predict the amount of our operating expenditures. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, results and costs of preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of drug candidates;
- the costs of future activities, including drug sales, medical affairs, marketing, manufacturing and distribution, for any drug for which we receive marketing approval;
- the costs of establishing and maintaining arrangements with third party manufacturers for the commercial supply of products that receive marketing approval, if any;
- the revenue, if any, received from commercial sale of our products, should any drug candidates receive marketing approval;
- the cash requirements of any future acquisitions or discovery of drug candidates;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the cost of implementing operational, financial and management systems;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, current or future drug candidates, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other variables with respect to the development of ACR-368, the ACR-368 OncoSignature, or any drug or development candidate we may develop in the future could significantly change the costs and timing associated with our development plans. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial drug revenues to support our expenses, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market our drug candidates even if we would otherwise prefer to develop and market such drug candidates ourselves.

Contractual Obligations

Leases

We lease laboratory and office space in Watertown, Massachusetts. This lease is classified as an operating lease, and will expire in April 2028, with an option to extend the term for an additional five years at then-market rental rates. Additionally, we also lease laboratory and office space in Lund, Sweden. This lease is classified as an operating lease, and will expire in September 2023, with an option to extend the term for an additional three years. Future minimum commitments under these leases are $7.2 million as of December 31, 2021. Of the $7.2 million, $1.1 million is due in less than 12 months. See Note 6 in our unaudited condensed consolidated financial statements appearing at the end of this prospectus for more information on our lease obligations.

License Agreement

We may incur contingent royalty and milestone payments that we are required to make under our license agreement with Lilly, pursuant to which we have in-licensed certain intellectual property. We are required to pay Lilly aggregate development and commercial milestone payments of up to $168.0 million, of which $5.0 million is due prior to NDA. Due to the uncertainty of the achievement and timing of the events requiring payment under our license agreement with Lilly, the amounts to be paid by us are not fixed or determinable at this time. We are also obligated to pay a tiered percentage royalty on annual net sales ranging from a low single-digit up to a maximum of 10%, subject to certain specified reductions. For additional information, see the section titled “Business—Licensing and Collaborations.”

Companion Diagnostic Agreement

We may incur contingent milestone payments that we are required to make under our companion diagnostic agreement with Akoya pursuant to which we agreed to co-develop, validate, and commercialize our proprietary ACR-368 OncoSignature test. We are obligated to pay Akoya up to an aggregate of $10.3 million upon the achievement of specified development milestones. Due to the uncertainty of the achievement and timing of the events requiring payment under our companion diagnostic agreement with Akoya, the amounts to be paid by us and when are not determinable at this time. While the achievement and timing of such milestones are uncertain, it is reasonably possible that up to $2.0 million in milestone payments could be achieved in the next 12 months. As of October 17, 2022, development milestones have been achieved under our companion diagnostic agreement, resulting in payments of $2.3 million by us to Akoya. For additional information, see the section titled “Business—Licensing and Collaborations.”

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs and other third-party vendors for clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service provided up to one year after the date of cancellation.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated 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 consolidated financial statements.

Research and Development Expenses

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

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

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

Preferred Stock Tranche Rights and Anti-dilution Right

The initial fair value of the Preferred Stock Tranche Rights recognized in connection with the issuance of our Series A-1 Preferred Stock in August 2020 and the Anti-dilution Right issued to Lilly in January 2021 were determined based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. These obligations were remeasured prior to the issuance of subsequent tranches in January 2021 and anti-dilution shares in November 2021 and at each interim reporting period. See Note 9 to our audited consolidated financial statements included elsewhere in this prospectus for additional information regarding our issuances of Preferred Stock.

The Preferred Stock Tranche Rights and Anti-dilution Right were valued as forward contracts. The values were determined using a probability-weighted present value calculation. In determining the fair values, estimates and assumptions impacting fair value included the future value of our Series A-1 Preferred Stock, risk free interest rates, estimated years to liquidity and probability of each milestone being achieved. We determined the per share future value of the shares of Series A-1 Preferred Stock by back-solving to the initial proceeds of the Series A-1 Preferred Stock financing. We remeasured each Tranche Right and Anti-dilution Right at each reporting period and prior to settlement.

Convertible Notes

We issued the Notes in 2018 and 2019 to investors, which were subsequently converted in October 2020. We elected the fair value option to account for the Notes. The fair value of the Notes was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. A change in the assumptions related to the valuation of the Notes could have a significant impact on the value of the obligation. The value was determined using a probability-weighted present value calculation. In determining the fair value of the Notes, estimates and assumptions impacting the fair value included the estimated future values of our Series A-1 Preferred Stock, discount rates, estimated time to conversion, and probability of conversion upon certain events. We remeasured the Notes at each reporting period and prior to the conversion of the Notes. There were no convertible notes outstanding during the year ended December 31, 2021.

Stock-Based Compensation Expense

We measure stock-based compensation based on the grant date fair value of the stock-based awards and recognize stock-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. For non-employee awards, compensation expense is recognized as the services are provided, which is generally ratably over the vesting period. At inception, prior to the issuance of any stock option grants, we adopted the guidance of Accounting Standards Update, or ASU, No. 2018-07, *Compensation—Stock Compensation* (Topic 718): *Improvements to Non-employee Share-based Payment Accounting*, ASU 2018-07, and account for awards to non-employees using the grant date fair value without subsequent periodic remeasurement.

Stock-based compensation expense is classified in our consolidated statements of operations based on the function to which the related services are provided or in the same manner in which the grantee's payroll costs are classified or in which the grantee's service payments are classified.

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 our expected dividend yield. As there is currently no public market for our common stock, we determined the volatility for awards granted based on an analysis of reported data for a group of guideline companies that 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. We expect to estimate expected volatility based on the group of guideline companies until we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our stock options granted to employees and non-employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. 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. We have not paid, and do not anticipate paying, dividends on our common stock; therefore, the expected dividend yield is assumed to be zero.

Determination of Fair Value of Common Stock

As there has been no public market for our common stock to date, the historical estimated fair value of our common stock has been determined by our board of directors, considering our most recently available independent third-party valuations of common stock. 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*, a third-party valuation firm prepared valuations of our common stock using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value. 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 exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. 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 hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more 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 our future values, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability-weighted to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuation of our common stock of $3.88 per share as of November 9, 2021, $3.63 per share as of April 15, 2022 and $4.07 per share as of July 22, 2022.

In addition to considering the results of the 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, which may be a date later than the most recent third-party valuation date, including:

- the prices at which we sold Preferred Stock and the superior rights and preferences of the Preferred Stock relative to our common stock at the time of each grant;
- our ability to raise future financings;
- the progress of our research and development efforts, including the status of clinical studies for our drug candidates;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into collaboration and license agreements;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event for the holders of our Preferred Stock and holders of our common stock, such as an IPO, or a sale of our company, given prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

There are significant judgments and estimates inherent in these valuations. These judgments and estimates include assumptions regarding our future operating performance, the stage of development of our drug candidates, the timing of a potential IPO or other liquidity event and the determination of the appropriate valuation methodology at each valuation date. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be 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.

Options Granted

The following table sets forth, by grant date, the number of shares underlying options granted from January 1, 2022 through the date of this prospectus, the per share exercise price of the options, the fair value per share of common stock on each grant date and the weighted-average estimated per share fair value of the options granted during the period:

Grant Date	Number of Shares Subject to Options Granted	Per Share Exercise Price of Options	Per Share Value of Common Stock on Grant Date	Weighted-Average Estimated Per Share Fair Value of Options
March 22, 2022	710,709	$ 3.88	$ 3.88	$ 2.50
June 27, 2022	486,613	$ 3.63	$ 3.63	$ 2.59
August 5, 2022	166,259	$ 4.07	$ 4.07	$ 2.93

The fair value of our common stock of $3.88 per share on March 22, 2022 was determined by our board of directors, based, in part, on the $3.88 per share value indicated in the third-party valuation prepared as of November 9, 2021. In particular, the valuation determined our enterprise value using an OPM backsolve approach that was based on the $5.71 price per share paid by new and existing investors in the closing of our Series B Preferred Stock financing in November 2021. A DLOM of the common stock was then applied to arrive at an indication of fair value for our common stock.

The fair value of our common stock of $3.63 per share on June 27, 2022 was determined by us, based, in part, on the $3.63 per share value indicated in the third-party valuation prepared as of April 15, 2022. In particular, the valuation determined our enterprise value using the hybrid method, which included a PWERM, with an IPO scenario, and a sale scenario. Our enterprise value in the IPO scenario was based on guideline IPO transactions identified within the last one to two years, which was adjusted by a risk-adjusted discount rate. The IPO scenario also assumed an estimated timeline for the IPO to occur. Our enterprise value for the sale scenario was based on an OPM market-adjusted backsolve method based on the $5.71 price per share paid by new and existing investors in the closing of our Series B Preferred Stock financing in November 2021. The negative market adjustment that was applied to the equity value considered the performance of guideline public companies and the biotech indices since the most recent sale of our preferred stock through the valuation date. A DLOM of the common stock was then applied to arrive at an indication of fair value for our common stock. In addition, the board determined that the fair value of our common stock remained at $3.63 per share through June 27, 2022. The decrease of $0.25 from the previous valuation performed at November 9, 2021 is primarily the result of a negative 20% market adjustment. The negative market adjustment applied was developed based on the share price declines noted for a range of comparable companies. The selected market adjustment applied to the enterprise value estimates the decline in enterprise values experienced in the market from November 2021 to April 2022.

The fair value of our common stock of $4.07 per share on August 5, 2022 was determined by us, based, in part, on the $4.07 per share value indicated in the third-party valuation prepared as of July 22, 2022. In particular, the valuation determined our enterprise value using the hybrid method, which included a PWERM, with an IPO scenario, and a sale scenario. Our enterprise value in the IPO scenario was based on guideline IPO transactions identified within the last one to two years, which was adjusted by a risk-adjusted discount rate. The IPO scenario also assumed an estimated timeline for the IPO to occur. The increase of $0.44 from the previous valuation performed as of April 15, 2022 is primarily the result of a probability increase for the IPO scenario. In particular, we began the formal process to prepare for a potential IPO, prior to our July 22, 2022 valuation.

On the effective date of the registration statement of which this prospectus forms a part, assuming we issue 5,900,000 shares in connection with this offering at an assumed price of $17.00 per share, we will issue certain directors and employees, including our executive officers, stock options to purchase an aggregate 1,008,493 shares of our common stock, under the 2022 Plan, subject to continued service through such grant date. Based on an assumed exercise price of $17.00 per share, which is the midpoint of the estimated price range set forth on the

cover page of this prospectus, we estimate that the aggregate grant-date fair value of the options to be granted in connection with this offering is $12.5 million, which is expected to be recognized as stock-based compensation expense over a period of three to four years.

In addition, on the effective date of the registration statement of which this prospectus forms a part, assuming we issue 5,900,000 shares in connection in this offering at an assumed price of $17.00 per share, we will grant certain employees, including our executive officers, an aggregate of 1,638,006 restricted stock unit awards, or RSUs, under the 2022 Plan, subject to continued service through such grant date. Based on an assumed fair value of $17.00 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, we estimate that the aggregate grant-date fair value of the RSUs to be granted in connection with this offering is $27.8 million, which is expected to be recognized as stock-based compensation expense over a period of three to four years.

The actual number of options and RSUs that we will grant upon the IPO is illustrative only and will change based on the actual initial public offering price and the actual number of shares that we issue in the offering.

See the sections titled "Management—Non-Employee Director Compensation Policy—Director IPO Option Grants" and "Executive Compensation—Outstanding Equity Awards at Fiscal Year End" for additional information.

Recent Accounting Pronouncements

A description of recent issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our unaudited condensed consolidated financial statements appearing at the end of this prospectus.

Internal Control Over Financial Reporting

In connection with the audit of our financial statements for the year ended December 31, 2021 and 2020, we identified material weaknesses in our internal control over financial reporting that existed as of those periods. See the section titled "Risk factors—We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business."

Qualitative and Quantitative Disclosures about Market Risk

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is impacted by changes to the general level of U.S. interest rates, particularly because our cash equivalents are in the form of money market funds that are invested in U.S. Treasury securities. As of June 30, 2022 and December 31, 2021, we had cash and cash equivalents of $83.9 million and $99.6 million, respectively. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

As of June 30, 2022 and December 31, 2021, we had no debt outstanding, and therefore we are not subject to interest rate risk related to debt.

Foreign Currency Exchange Risk

Our reporting currency is the U.S. dollar, or USD. Our functional currency for Acrivon AB, our wholly-owned subsidiary in Sweden, is the USD. Adjustments that arise from exchange rate changes on transactions

denominated in a currency other than the functional currency are included in other income (expense), net in the consolidated statements of operations and comprehensive loss as incurred. We have not recognized material currency transaction gains or losses during the six months ended June 30, 2022 and year ended December 31, 2021.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We believe that inflation has not had a material effect on our consolidated financial statements included elsewhere in this prospectus.

Emerging Growth Company and Smaller Reporting Company Status

The JOBS Act provides that, among other things, an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. As an emerging growth company, we have elected not to "opt out" of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for private companies on a case-by-case basis until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. We intend to rely on certain of the other exemptions and reduced reporting requirements provided by the JOBS Act. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), and (ii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

BUSINESS

Overview

We are a clinical stage biopharmaceutical company developing precision oncology medicines that we match to patients whose tumors are predicted to be sensitive to each specific medicine by utilizing our proprietary proteomics-based patient responder identification platform. Recently approved targeted oncology treatments, such as kinase inhibitors, have transformed the cancer treatment landscape, and while the therapeutic benefit of these agents has provided significant benefit to patients, these targeted oncology treatments unfortunately only address the less than 10% of patients with cancers that harbor certain easily-identifiable genetic mutations. Our approach is designed to overcome the limitations of genomics-based patient selection methods. We do this by using our proprietary precision medicine platform, Acrivon Predictive Precision Proteomics, or AP3, to develop our pipeline of oncology drug candidates. Our AP3 platform enables the creation of drug-specific proprietary OncoSignature companion diagnostics that are used to identify the patients most likely to benefit from our drug candidates, which we refer to as patient responders. We are currently advancing our lead candidate, ACR-368, a selective small molecule inhibitor targeting CHK1 and CHK2 with sub single-digit nM and single-digit nM potency, respectively, in a potentially registrational Phase 2 trial across multiple tumor types, which our AP3 platform predicts will have a high proportion of patient responders based on OncoSignature-predicted sensitivity to ACR-368. Our ACR-368 OncoSignature test, which has not yet obtained regulatory approval, has been extensively evaluated in preclinical studies, including in two separate, blinded, prospectively-designed studies on pretreatment tumor biopsies collected from patients with ovarian cancer treated with ACR-368 in past Phase 2 clinical trials conducted by Eli Lilly and Company, or Lilly, and at the National Cancer Institute, or NCI, demonstrating robust enrichment of responders through our method.

The AP3 approach is proteomics-based and designed to enable identification and treatment of the patients whose tumors are sensitive to a specific drug or drug candidate based on direct protein measurement of critical tumor-driving mechanisms and independent of underlying genetic alterations. We believe our approach is applicable across stages of drug development and across therapeutic modalities. Accordingly, the AP3 method is not limited to the typically very small subset of cancers driven by single gene driver mutations or susceptible to a synthetic lethal approach. Rather, we believe our method is broadly applicable to the vast majority of cancers, in particular the majority of solid tumors, for which genetics-based approaches have proven insufficient to identify patient responders in many cases. In principle, we believe a much larger percentage of tumors can be addressed therapeutically using agents attuned to the specific biochemical signaling pathways found in these tumors, which our AP3 platform was purposefully designed to enable.

By applying our highly specific patient selection approach to drug development, we seek to both accelerate clinical development and significantly increase the probability of successful treatment outcomes for patients. Our pipeline includes the Phase 2 lead program, ACR-368, also known as prexasertib, a targeted oncology asset that targets CHK1 and CHK2, or CHK1/2. ACR-368 has been dosed in more than 400 patients at the recommended Phase 2 dose, or RP2D, with reported deep, durable responses, including complete responses, or CRs, in a proportion of patients with solid tumors in past single center and multi-center Phase 2 clinical trials in tumor indications with high unmet need. ACR-368 has also demonstrated a generally favorable safety and tolerability profile with primarily reversible hematological toxicity and very limited non-hematological toxicity. We have received clearance from the U.S. Food and Drug Administration, or FDA, for an Investigational New Drug, or IND, application to advance ACR-368 in Phase 2 single arm clinical trials conducted under the FDA program known as the master protocol, which was developed to help expedite drug development in multiple tumor types for drugs with an established RP2D within the same overall trial structure. Initially, patients with platinum-resistant ovarian, endometrial, or bladder cancer will be treated in this trial. Patients will be stratified for treatment based on OncoSignature-predicted sensitivity to ACR-368 across multiple sites in the United States in this trial with registrational intent. Through the use of our OncoSignature test, we believe we can significantly increase the overall response rate, or ORR, observed in previous trials that were conducted without a prospective patient responder identification method. We also plan to study ACR-368 in additional indications, such as human papilloma virus positive, or HPV^{+}, squamous cell carcinomas, including squamous cell cancer, or SCC, of head and neck, or SCCHN, anal, and cervical cancer, based on demonstrated clinical single agent activity in SCCHN

and anal cancer and OncoSignature-based prediction of sensitivity to ACR-368 in a proportion of patients. In addition to ACR-368, we are also developing internally-discovered preclinical stage pipeline programs targeting critical nodes in the DNA Damage Response, or DDR, and cell cycle regulation pathways, including WEE1, a protein kinase, and PKMYT1, a closely related protein serine/threonine kinase.

We were founded and are led by pioneers in oncogenic signaling, oncology precision medicine and the use of proteomic technology to uncover intracellular biochemical signaling pathways with the goal of applying this knowledge to develop drug candidates and clinical diagnostics. Our founders have established proof-of-concept, including clinical implementation, for the underlying technologies in our AP3 platform. Our scientific advisors are thought leaders from leading global cancer and academic centers and are actively involved in our drug development process. We are supported by leading healthcare investors, including Wellington Management, Surveyor Capital, RA Capital, Perceptive Advisors, Sands Capital and Chione. Prospective investors should not rely on the past investment decisions of our investors, as our investors may have different risk tolerances and have received their shares in prior offerings at prices lower than the price offered to the public in this offering.

Our AP3 Platform

Our AP3 platform is based on our proprietary approach developed to enable treatment of the patients who are most likely to respond to any particular drug candidate based on dependency in the tumor on the upregulated specific biochemical pathways that each drug modulates. Hence, our approach is tumor-agnostic: if the pathways the tumor depends on for its survival and growth, and that the drug candidate modulates, are upregulated, we predict that individual patient's tumor will be sensitive to the drug candidate. This applies regardless of the tumor origin and is independent of underlying genetic alterations. We are applying AP3 broadly to clinically active drug candidates as well as carefully selected preclinical lead series with a strong clinical rationale, and for which there is no obvious patient selection path through standard companion diagnostic approaches. We also intend to explore the use of AP3 with approved drugs to improve the ORR and outcomes for patients through our patient selection approach.

One of the key outputs of our AP3 platform are our proprietary response-predictive clinical tests that we refer to as OncoSignature tests. These are drug-tailored, automated, quantitative proteomic tissue imaging tests applied to pretreatment tumor biopsies as a companion diagnostic, or CDx, to select and treat the patients predicted to benefit from the drug candidate. Our OncoSignature test, which has not yet obtained regulatory approval, is being developed with Akoya Biosciences, Inc., or Akoya, pursuant to a companion diagnostic agreement. Our OncoSignature tests encompass a signature of three classes of functionally-defined protein biomarkers assembled into a single signature assay. The quantitative levels for each of the three biomarkers are defined to determine whether a patient's individual tumor has upregulated the biochemical signaling mechanisms that the drug modulates and that the tumor depends on for growth and/or survival. Our company name, Acrivon, is derived from Greek for "accurate." We chose it to embody how our OncoSignature tests are designed to accurately match our therapies with patients who will benefit.

The tumor-agnostic application of OncoSignature tests enables us to identify and focus on tumor types for which a high unmet need for a treatment exists and that are predicted to be highly sensitive to our drug candidates. We achieve this by deploying our OncoSignature screening of human cancer samples across various tumor types. Through this process, we can identify new tumor types predicted to be sensitive to a drug candidate and even estimate the percentage of predicted responders before entering clinical trials. For example, we have identified endometrial cancer and bladder cancer as two highly sensitive cancer types for ACR-368, and therefore will include patients with these tumor types in our Phase 2 trials. Moreover, we have found through this approach that a proportion of patients with HPV^{+} cancers are predicted to be responsive to ACR-368, consistent with previously demonstrated clinical activity in a proportion of patients with SCCHN and anal cancer. Furthermore, we predicted that patients with squamous non-small cell lung cancer, or sqNSCLC, would not respond to ACR-368, consistent with an observed ORR of 0% in patients with this tumor type in a past trial with ACR-368. Hence, through our OncoSignature screening approach, we can specifically avoid running clinical trials in cancer types predicted to have limited sensitivity to the drug candidate.

We are not only using our AP3 platform to generate drug-tailored, response-predictive clinical OncoSignature tests, but we also use our AP3 platform to provide unbiased, quantitative analyses of off-target effects on intracellular signaling using phosphoproteomic profiling, potentially enabling us to discover inhibitors that are both highly potent and highly selective.

We believe that by leveraging our AP3 platform and clinical OncoSignature tests, we will profoundly alter precision oncology drug development and the treatment landscape of patients suffering from cancer.

Our Pipeline

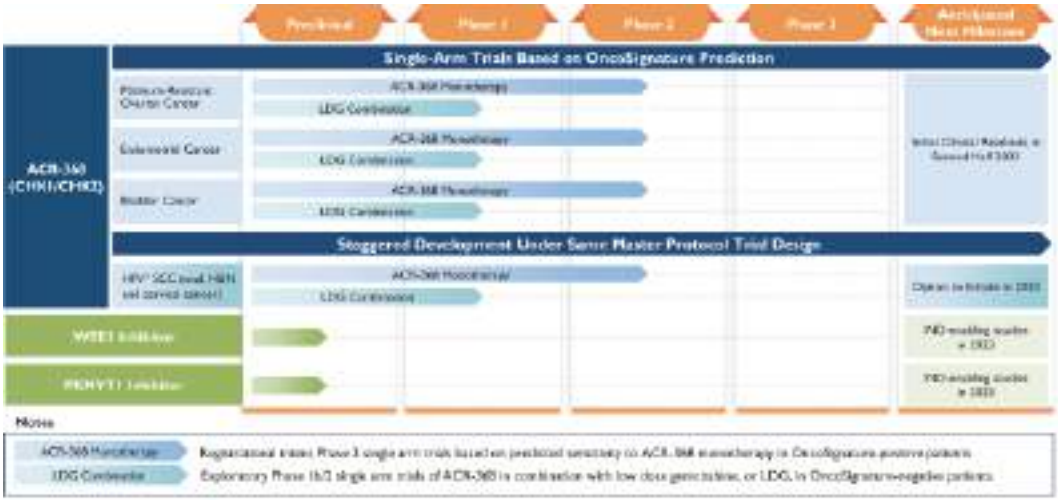

Figure 1. Acrivon's internal pipeline including the clinically advanced ACR-368 and two preclinical programs.

Our Lead Clinical Candidate ACR-368

ACR-368 is a selective small molecule inhibitor targeting CHK1/2. CHK1/2 are key regulators of the cell cycle and of DDR and inhibition of CHK1/2 has been demonstrated to have anti-tumor activity in multiple preclinical models as well as in clinical trials in humans. Several CHK1/2 inhibitors including ACR-368, also known as prexasertib, have been investigated in the clinic; however, none have been approved by the FDA. ACR-368 has shown deep, durable single agent clinical activity, including CRs and partial responses, or PRs, in a proportion of patients with solid tumors with high unmet need for a treatment, such as platinum-resistant ovarian cancer, and SCCs, including SCCHN and anal cancer. More than 400 patients with these tumors have been treated with ACR-368 monotherapy at the RP2D in advanced single- and multi-center clinical trials conducted by Lilly, NCI, and at MD Anderson Cancer Center, or MDACC. The ORR in these trials without a predictive biomarker was 29% at the single center Phase 2 ovarian cancer trial at NCI in the intent to treat, or ITT, population, and approximately 12% across the platinum-resistant ovarian cancer cohorts in the large Phase 2 multi-center international trial sponsored by Lilly. The median duration of response, or mDOR, at the RP2D across trials to date have ranged from almost six months to 12 months, and ACR-368 monotherapy demonstrated a generally favorable safety and tolerability profile with primarily reversible hematological toxicity and very limited non-hematological toxicity. Based on these two trials, encompassing over 200 patients with ovarian cancer, primarily platinum-resistant, we believe the unenriched background ORR in a larger patient population of platinum-resistant ovarian cancer is somewhere between 15% and 20%.

Using our AP3 platform, we have developed a predictive OncoSignature test for ACR-368, called ACR-368 OncoSignature, that we believe can predict patient response to ACR-368 monotherapy and therefore substantially

improve the clinical ORR and, furthermore, that we believe, has the potential to enable expedited drug development. Predicted patient responders are referred to as ACR-368 OncoSignature-positive and predicted non-responders are referred to as ACR-368 OncoSignature-negative. The ACR-368 OncoSignature test has been extensively evaluated in preclinical studies in both patient-derived xenograft, or PDX, mouse tumor models as well as in two separate blinded, prospectively designed preclinical studies of pre-treatment tumor biopsies collected from patients with ovarian cancer that received ACR-368 in previous clinical trials. Based on the preclinical study results, we believe the ORR in the ACR-368 OncoSignature-positive patients will be increased significantly when compared to the unenriched ORR observed in previous trials.

By applying our ACR-368 OncoSignature test for indication finding and expansion across human cancer types, as described below, we have found that approximately 30% of samples from patients with ovarian cancer are ACR-368 OncoSignature-positive. Moreover, we observed that between 30% and 40% of patients with endometrial and bladder cancer are predicted to be highly sensitive to ACR-368. Patients with these two types of cancer were not previously treated in ACR-368 clinical trials. All three tumor types are therefore included in our upcoming Phase 2 clinical trial.

We have also used our AP3 platform to identify resistance mechanisms to ACR-368. Through phospho-proteomic profiling of human tumor cell lines that are either highly sensitive or highly resistant to ACR-368, we uncovered key resistance mechanisms and found that very low dose gemcitabine, or LDG, could be used to overcome resistance and further sensitize human tumor cells to ACR-368 through inducing increased DDR stress. Moreover, the use of LDG was observed to enhance sensitivity to ACR-368 in the already sensitive cells. We expect this may enable ACR-368 in combination with LDG to be an important treatment for ACR-368 OncoSignature-negative patients who would otherwise be excluded from ACR-368 treatment.

Based on these results, we are initiating a Phase 2 clinical trial where we intend to treat patients with all three tumor types: platinum-resistant ovarian, endometrial, and bladder cancer. ACR-368 OncoSignature-positive patients, which we believe will represent 30% to 40% of patients of each tumor type, will receive ACR-368 monotherapy in a single arm Phase 2b trial for each of the three tumor types. The ACR-368 OncoSignature-negative patients with one of these three tumor types will receive ACR-368 combined with LDG in a Phase 1b trial, followed by expansion into a Phase 2 trial with the combination in all three tumor types. As a result, all patients with these tumor types that have been biopsied will be eligible to receive therapy. This Phase 2 clinical trial design and protocol has been cleared by the FDA and we have begun enrolling patients. Akoya will procure and manufacture the necessary supplies to perform the OncoSignature tests used in the Phase 2 clinical trial. Based on our communications with the FDA to date, we believe this trial, if successful, has the potential to be registrational for ACR-368 in each of the three tumor types.

We are carrying out our trial under the auspices of the master protocol guidance issued by the FDA in March 2022 to enable expedited drug development. This guidance provides sponsors of drugs or biologics for the treatment of cancer and for which the RP2D has been established in prior studies, the opportunity to simultaneously evaluate more than one investigational drug and/or multiple cancer subpopulations within the same overall trial structure under master protocol in adult and pediatric cancers.

We believe that use of our ACR-368 OncoSignature test to select patients predicted to be sensitive to ACR-368 for treatment will significantly increase the ORR, which has the potential to lead to accelerated approval for multiple cancers while avoiding treatment of patients with tumors that are not likely to respond. However, we cannot guarantee that the FDA will permit us to utilize an expedited approval process or that our intended approach will be sufficient for regulatory approval. We are planning to file an IND application amendment to add three additional cancer types under the same trial protocol design at a later time, including head and neck cancer, anal cancer, and cervical cancer.

Our Preclinical Programs

We also have two preclinical drug programs designed to take advantage of our AP3 platform and the ability to predict tumor sensitivity based on custom OncoSignature tests. Both of these programs are structure-guided with rational medicinal chemistry efforts based on co-crystallography of lead series with their respective targets.

The first of these is directed at WEE1, a critical node in the DDR pathways. WEE1 inhibitors have demonstrated promising anti-tumor activity in early clinical trials conducted by competitors; however, the ORRs have been relatively low and we believe will be insufficient for approval without a patient selection method. Similar to the case with ACR-368, to our knowledge, no genetic biomarkers have been identified that can reliably predict drug sensitivity. Multiple lead compounds have been synthesized and co-crystallized with WEE1 at high resolution, resulting in four novel lead series with single-digit nM potency that have preclinical pharmacokinetic, or PK, studies ongoing.

The second, equally advanced preclinical program is directed at PKMYT1, a closely related protein serine/threonine kinase also serving critical functions in the cell cycle and DDR pathways. Based on mechanism of action and preclinical studies there is a rationale and data suggesting that inhibition of PKMYT1 will result in clinical activity. Currently one company has advanced a PKMYT1 inhibitor into phase 1 clinical trials. We believe the compound is in need of a patient selection method in the clinic and that genetics-based patient selection methods will be challenging. Similar to the WEE1 program, many high resolution co-crystals have been generated between our lead series and PKMYT1, resulting in two promising, equally potent, novel lead series with PK studies ongoing.

Based on results from our AP3 platform, we believe that we can predict drug-sensitivity using our proteomics-based approach for patient responder identification with our OncoSignature tests. We anticipate advancing our WEE1 inhibitor and PKMYT1 inhibitor into IND-enabling studies in 2023.

AP3 Potential for Broad Clinical Impact

Our AP3 platform is based on two integrated technology pillars, mass spectrometry-based proteomic profiling and our automated tumor imaging biomarker platform. Mass spectrometry, or MS, enables a systematic, unbiased quantitative analysis of the proteins inside a cell or entire tissues and is used to identify our biomarker candidates. These are validated using our biomarker platform which is also used to run our OncoSignature tests. AP3 is designed to generate multiple clinically-actionable, valuable outputs:

- Predictive biomarkers and patient responder identification: Our OncoSignature tests are designed to enable identification and treatment of patients predicted to be sensitive to the drug candidate, while avoiding treatment of patients predicted not to benefit.
- Indication finding and expansion: OncoSignature screening of human patient tumor samples is used to predict what proportion of various tumor types are expected to be highly sensitive to our drug candidates. This enables indication expansion and could potentially increase the response rates in clinical trials.
- Identification of resistance mechanisms: AP3 is a powerful technology to identify either pre-existing (intrinsic) resistance or acquired (therapy-induced) resistance to drugs demonstrated in prior studies. We intend to apply this technology to develop combination therapy candidates that target the druggable resistance mechanisms and re-sensitize tumors and to prevent resistance development.
- Identification of rational drug combinations: Through our AP3 platform, we uncover the entire protein signaling pathways underlying resistance. The druggable targets on such pathways are a basis for rational drug combinations and we believe can efficiently overcome resistance demonstrated in multiple prior studies. We intend to apply this for indication expansion and confirmatory trials for our drug candidate pipeline.

- Unbiased drug target engagement and pharmacodynamic biomarker discovery: Through our high resolution phosphoproteomic drug profiling, we uncover thousands of on- and off-target interactions and drug-regulated pharmacodynamic, or PD, biomarkers for each drug candidate. These can be used to guide selectivity optimization of preclinical lead series and to measure drug target engagement in patient tumor tissues during clinical trials, and hence guide dose optimization.

Our AP3 platform deploys high resolution, high throughput MS resulting in large datasets reflecting differentially drug-regulated phosphorylation sites and signaling pathways inside sensitive and resistant cells for each drug candidate we profile. The data are highly structured and amenable to machine learning, which has enabled us to create a streamlined process and to integrate all the analytical steps into a single workflow. We intend to apply our AP3 platform to both our existing and future pipeline of drug candidates addressing prevalent, high unmet need cancers and where patient responder identification has proven challenging, as further described below.

Figure 2. AP3 has potential for broad impact across the drug discovery and development process.

Our Team

We were founded and are led by pioneers in oncogenic signaling, oncology precision medicine, and the use of proteomic technology to uncover intracellular biochemical signaling pathways and to apply this knowledge to develop drug candidates and clinical diagnostics. Peter Blume-Jensen, MD, PhD, our co-founder, President and Chief Executive Officer, is the inventor of our AP3 platform and OncoSignature patient selection method. He has extensive experience in oncology drug discovery and development at leading pharmaceutical companies including Serono, Merck & Co. and Daiichi Sanyo. While Chief Scientific Officer at Metamark Genetics, Dr. Blume-Jensen led the development of an automated, proteomics-based predictive clinical diagnostic for prostate cancer which was validated through blinded clinical trials and included as the only stand-alone test under National Comprehensive Cancer Network, or NCCN, guidelines and reimbursement in 2015. Kristina Masson, PhD, co-founder, Executive Vice President, Business Operations and head of our discovery research site in Sweden, previously founded and operated OncoSignature AB, a biotech company which established the phosphoproteomics and drug discovery infrastructure, and which we subsequently acquired. Jesper Olsen, PhD, our academic co-founder, is Professor of Quantitative Proteomics at the University of Copenhagen and Vice

Director of the Novo Nordisk Foundation for Protein Research and a recognized pioneer of MS-based quantitative phosphoproteomics. Rasmus Holm-Jorgensen, our Chief Financial Officer, has over 20 years of experience in the biopharmaceutical industry, most recently as Chief Strategy & Portfolio Officer and part of the founding team at Kiniksa Pharmaceuticals. Erick Gamelin, MD, PhD, our Chief Medical Officer, has led over 100 Phase 1 through Phase 3 oncology clinical trials and most recently served as Chief Medical Officer of Step Pharma. Eric Devroe, PhD, our Chief Operating Officer, has extensive experience in operations and business development leadership from his time at Metamark Genetics, MDACC, and several start-up companies.

Our founders have pioneered and established proof-of-concept, including clinical implementation, for the underlying technologies in our AP3 platform.

Our Strategy

Our goal is to be the leading biopharmaceutical company leveraging proteomic and phosphoproteomic data, which we access through our proprietary AP3 platform, to unlock insights beyond genomic-based approaches and discover and efficiently develop medicines to benefit patients with cancer.

While our AP3 approach is broadly applicable across disease areas, we are initially committed to oncology. Our goal is to treat patients with cancer with clinically active therapeutics that have a high likelihood of success based on predicted sensitivity to our drug candidates. Oncology is an area of high unmet clinical need, in which only a small fraction of patients currently benefit from existing predictive biomarkers, such as next-generation sequencing, or NGS. We are currently applying the AP3 technology to both in-licensed clinical stage and to internally developed drug candidates for tumors that do not harbor single gene driver mutations, which is estimated to be more than 90% of all human cancers. The relevant drug target classes in these tumors that we believe are well-suited for our AP3 approach include but are not limited to DDR pathways, DNA replication stress, super enhancers, and cell cycle and transcriptional regulators. We are initially focused on expedited clinical development of our clinically advanced asset ACR-368, in our upcoming Phase 2 trial in patients with platinum-resistant ovarian, endometrial, or bladder cancers, followed by staggered development of ACR-368 in HPV^{+} cancers. This trial is based on OncoSignature-predicted sensitivity to ACR-368 and has recently been cleared by the FDA to be conducted under a master protocol. In addition, we intend to leverage AP3 for our internally developed preclinical programs targeting WEE1 and PKMYT1. The key elements of our strategy summarized below are to:

- **Advance ACR-368, our CHK1/2 inhibitor, through clinical development in ovarian, bladder, and endometrial cancer by enrolling ACR-368 OncoSignature-positive patients**. Our lead program, ACR-368, has already demonstrated deep, durable anti-tumor activity, including CRs, in patients with ovarian cancer in past clinical trials. Based on our robust preclinical data, including in two blinded, prospective studies on pretreatment tumor biopsies from past ovarian cancer trials with ACR-368, we believe that our ACR-368 OncoSignature test will lead to significant improvement in ORRs in ovarian cancer as compared to the ORR seen in the previous trials. Based on human tumor sample profiling, we expect around 30% of patients with ovarian cancer to be ACR-368 OncoSignature-positive and these patients will receive ACR-368 monotherapy in a single arm Phase 2 clinical trial. Additionally, through screening with our ACR-368 OncoSignature test we predict that patients with other solid tumor types of high clinical unmet need, including 30% to 40% of patients with endometrial and bladder cancer, could benefit from ACR-368 monotherapy. We have further confirmed this prediction in preclinical studies on PDX models of these two tumor types where we observed that these tumors were highly sensitive to ACR-368, and that our ACR-368 OncoSignature test was able to prospectively identify which models are the most sensitive. We have begun enrolling patients in Phase 2 clinical trials in these tumor types and expect to report initial clinical data from this trial during the second half of 2023. Pending the results and discussions with the FDA, we intend to enter the registrational phase during 2024.
- **Selectively pursue AP3 identified rational drug combinations with our drug candidates in OncoSignature-negative patients, initially ACR-368 with LDG**. Our AP3 platform is able to elucidate pathways of underlying tumor resistance mechanisms, both pre-existing (intrinsic) and

acquired (therapy-induced). This allows us to identify rational drug combinations that can re-sensitize ACR-368 OncoSignature-negative patients to our drug candidates in resistant tumors. For example, we have shown that LDG was highly synergistic with ACR-368 in resistant human tumor cell lines and was able to re-sensitize ACR-368 resistant tumors to ACR-368, in ovarian, bladder, and endometrial cancers. Based on these findings, we will conduct a clinical trial with ACR-368 in combination with LDG for patients that are ACR-368 OncoSignature-negative within these tumor types, and subsequently in patients with HPV^+ cancers. We have begun enrolling patients into a Phase 1b dose escalation arm, in order to determine the optimal dosage of LDG with the RP2D of ACR-368, and then expand into a Phase 2 trial.

- **Discover and develop a pipeline of proprietary drug candidates by leveraging our AP3 platform and predictive OncoSignature tests**. We are applying our AP3 platform in multiple ways to build and advance a pipeline of structure-guided, wholly owned precision oncology drug candidates. Our first earlier stage pipeline program is targeting WEE1. While WEE1 inhibitors have shown single agent clinical activity across patients with solid tumors of high unmet need, the ORR so far has been insufficient for approval and, despite significant efforts in identifying patient responders, these efforts have not been fruitful to date. We believe that with our AP3 platform and OncoSignature patient selection strategy, we can significantly enrich the ORR for responders sufficient for approval. Our WEE1 program is currently in preclinical stage and we expect to enter IND-enabling studies during 2023. We are also developing an additional preclinical stage lead series in parallel against PKMYT1. Based on mechanism of action and preclinical studies there is a rationale and data suggesting that inhibition of PKMYT1 will result in clinical activity. Currently one company has advanced a PKMYT1 inhibitor into phase 1 clinical trials. We believe the compound is in need of a patient selection method in the clinic and that genetics-based patient selection methods will be challenging. We expect to enter IND-enabling studies for that program in 2023. All of our internally derived drug candidates will leverage AP3 phosphoproteomic drug candidate profiling to guide and optimize drug potency and selectivity. We believe that this approach will help ensure that our drug candidates directly affect the pathways of interest while minimizing off-target effects, an approach that is highly differentiated from traditional drug discovery programs. Secondly, by developing OncoSignature tests tailored for our pipeline drug candidates we believe we can identify patients with highly sensitive tumor types of high unmet clinical need for treatment before initiation of our clinical trials.
- **Acquire rights to drug candidates for which we believe our OncoSignature tests can increase the likelihood of clinical success**. We in-licensed ACR-368 after successfully developing a predictive ACR-368 OncoSignature test to increase the probability of clinical success. We intend to take a similar approach and in-license other attractive drug candidates where genetics-based patient selection is challenging or impossible, and develop drug-tailored OncoSignature tests for these drug candidates. We intend to pursue only the opportunities that, similar to ACR-368, have high clinical potential and where we believe we can successfully select patients who are likely to respond to such specific drug candidates, based on our proprietary OncoSignature tests.
- **Opportunistically enter into strategic co-development partnerships around predictive OncoSignature tests to maximize the full potential of our AP3 platform**. We believe that there are opportunities to partner with organizations that have approved drugs or drug candidates in development under competitive pressure and where the availability of a highly predictive OncoSignature test to achieve high ORRs can potentially provide an advantage in obtaining regulatory approval and market share. Moreover, we believe that identification of rational drug combinations for such drugs to improve ORR and clinical benefit are of high value to prospective partners. We intend to pursue such partnerships where we can realize the value that OncoSignature and our AP3 platform can bring to the drug candidate through early co-development.

Urgent Need for Precision Oncology Approaches that Transcend the Limitations of Genomics

Cancer is a disease of dysregulated protein activity, which occurs as a result of underlying genetic changes. The majority of precision medicine efforts in oncology have been focused on identifying patients who are most likely to respond based either on genetic changes in their tumors, such as specific mutations, gene amplifications, and gene translocations, or on the patient's own genetic background. The availability of genomic sequences from tens of thousands of tumors has begun to transform oncology treatment away from the use of broad cytotoxic drugs approved based on tumor location towards precision medicines that address tumors with specific genetic alterations. However, while this approach has led to the recent approval of a number of targeted therapies, their use is limited to a very small fraction of patients with these mutations. It is estimated that only 9% of all patients with cancer have tumors with genetic profiles that make them eligible for an available precision oncology medicine, so-called genetically-defined cancers, and only 5% of all patients with cancer are likely to benefit from available therapies.

Figure 3. Proteomic biomarkers have the potential to be broadly applicable across the vast majority of cancers.

Proteomic biomarkers have the potential to be broadly applicable for the vast majority of cancers where more traditional genetics-based approaches have proven challenging. In this small subset of genetically defined cancers, most often the alterations in the gene lead to drug target protein dysregulation that drives the cancer, which are potential targets of cancer therapies. There are three main types of such recurrent single driver gain-of-function, or GOF, gene alterations known in human cancer: point mutations, gene fusions, and amplifications, which represents less than 10% of all cancers. These most easily addressable GOF mutation-driven cancers have been the obvious focus of drug discovery and development for more than two decades. Examples of such approved drugs include Vemurafenib for B-RAF-V600E-mutant melanoma, Imatinib for KIT and PDGFR-alpha mutant GIST, Crizotinib for EML4-ALK+ lung cancer, Trastuzumab for HER2 amplified breast cancer, and recently Larotrectinib for solid tumors with N-TRK fusions. However, more than 90% of cancers have tumor-driving targets that do not harbor underlying single genetic alterations. Such tumor-driving drug targets are activated through post-translational modifications, including phosphorylation, due to complex genetic alterations elsewhere in the genome of tumor cells, rather than in the drug target itself. Successful clinical development of inhibitors for these targets is highly challenging as prevailing predictive methods such as NGS, polymerase chain reaction, or PCR, fluorescent *in-situ* hybridization, or FISH, immunohistochemistry, or IHC, and transcriptomics have not been successful in identifying patients that would significantly benefit from the drug.

Accordingly, while a powerful tool to uncover underlying mechanisms of disease, the utility of genomics for patient selection is limited when it comes to drug response prediction in oncology. Additionally, the lack of

therapeutic efficacy for a given drug, due to inability to identify patient responders, is still a top attrition factor in drug development. The vast majority of cancers contain multiple, complex genomic alterations resulting in the dysregulated, tumor-driving protein activity. Relatively few genetic alterations are common to a broad percentage of patients with cancer, such as mutations in the K-RAS or p53 genes. However, precision medicines against these targets have been difficult to develop and, because of the complex genetic alterations often co-existing in tumors, treatment often does not elicit expected clinical benefit.

The AP3 Solution: Matching Drug Action to the Disease-driving Mechanisms in Patients' Tumors

Our AP3 platform has been developed over the last decade to be an efficient process and workflow to determine sensitivity to drugs based on the biological signaling pathways that are activated in diseased cells and are required for their survival. Our AP3 platform leverages proteomic biomarkers which enable direct measurement of disease-driving mechanisms independent of target gene alterations, and allow for accurate matching with the mechanism of action of a particular drug. For example, in the case of ACR-368, which is a selective CHK1/2 inhibitor, the three biomarkers we quantify with our ACR-368 OncoSignature assay measure the level of activated DNA repair downstream of the activated drug targets and whether the tumor likely depends on it. One biomarker is a specific phosphorylation site in the drug target and another is a specific phosphorylation site in a key DNA repair protein, which together inform us about their functional activity. The third is a protein that drives premature DNA replication, which implies that the tumor is dependent on the upregulated DNA repair measured by the two other biomarkers. We have designed our proprietary AP3 platform to be agnostic to the underlying genetic alterations in the genome and enable identification and treatment of patients based on direct measurement of the disease-driving mechanisms that are regulated by and sensitive to the drug. Hence, in contrast to measuring genetic alterations in a patient's tumor, which is only a surrogate read-out for protein dysregulation, and having to infer whether the drug will act on the inferred protein dysregulation, the AP3 method directly reveals the dysregulated proteins and pathways driving the tumor that the drug acts on. The AP3 method is drug-centric, and we believe enables an accurate match *(*Acrivon is derived from Greek for "accurate") between the mechanism of the drug action with the disease-driving mechanisms in the patient's tumor.

Figure 4. We are applying AP3 to develop drug candidates with the potential to serve the high unmet clinical needs of the 95% of patients currently unaddressed by precision oncology.

Our AP3 platform is fundamentally different from genetics-based methods to identify patient responders and we believe it is particularly applicable to the majority of cancers without genetic alterations in the drug target itself. It specifically focuses on the proteins and pathways that drive tumor growth and survival and enable drug action, rather than exploring complex biology and accumulated genetic alterations that have proven very difficult to connect to drug response.

While the principles and technology behind AP3 are not limited to cancer, we are initially committed to oncology, where we are applying AP3 to develop drug candidates with the potential to transform the treatment of solid tumors of high unmet clinical need. Strategically, we are applying AP3 to drug classes where genetics has proven difficult or insufficient for response prediction, and that are active in major fractions of solid tumors, but where the ORR is insufficient for approval without a prospective patient responder identification method. In addition to DDR pathway inhibitors such as ATR, ATM, WEE1, and CHK1/2, examples of drug classes that we believe would benefit from our AP3 platform include cell cycle regulators (such as CDK2, 4, 6), mitotic regulators (such as Aurora kinases), transcriptional regulators, DNA replication modulators, such as CDC7, super enhancer kinases (such as CDK7, 9, 12), and inhibitors of mutated forms of K-RAS. We believe our ability to apply AP3 to these drug classes allows us to open up the potential of precision medicine approaches to a much

larger fraction of patients than has been possible using exclusively genetics-based approaches. We are initially progressing a pipeline of DDR drug candidates, but intend to broaden our pipeline to some of these other drug classes and targets through OncoSignature patient responder identification.

Our AP3 platform is based on two underlying technology pillars typically executed in two sequential steps: the first step, a high-resolution MS for biomarker identification which is integrated with, the second step, our automated tumor biopsy-imaging biomarker platform that enables biomarker validation and which is also used to run our OncoSignature tests.

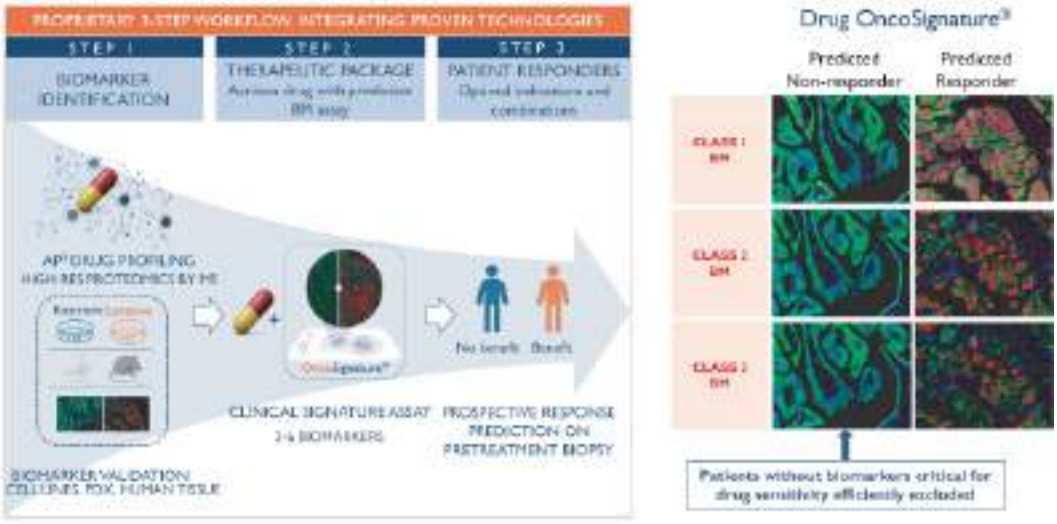

Figure 5. Our AP3 platform is based on unbiased biomarker identification using global phosphoproteomic profiling by MS and an automated biomarker platform for our clinical OncoSignature tests.

MS enables a systematic, unbiased quantitative measurement and analysis of the proteins inside a cell or entire tissues. We specifically use it to identify and measure in an unbiased manner the effects of any given drug or drug candidate on the activity state of the protein signaling networks inside a cell through analysis of the phosphorylation state and levels of proteins inside a tumor cell. Phosphorylation is the best-studied, allosteric on-off switch regulatory mechanism for protein activity involved in all forms of intracellular signaling. Analysis of the entire phospho-proteome before and after drug treatment, so-called phosphoproteomic drug profiling, enables us to objectively identify the global effect of any drug on the activity state of the protein signaling network.

Our MS efforts allow us to identify attractive drug-regulated biomarker candidates, which include identifying changes in overall protein levels as well as in post-translational modifications of proteins, such as those that involve phosphorylation and are involved in activation or inhibition of protein function in biological signaling pathways. Our data-independent acquisition, label-free phosphoproteomic methods provide for very high resolution. Starting with lists of thousands of potential biomarker candidates that correlate with drug sensitivity and resistance, our proprietary algorithms and workflows distill biomarker candidates into three functionally defined classes. The biomarkers are further validated in tumor models and through quantitative measurements on PDX models as well as on patient tumor samples and, when available, clinical trial biopsies, as we have done with ACR-368.

Use of our AP3 platform to develop drug-tailored, predictive OncoSignature tests

One of the key outputs of our AP3 platform are our drug-tailored OncoSignature tests, which are based on an assembly of biomarkers from each of the three classes selected by the process described above, resulting in a

single, quantitative signature test. They are automated, quantitative protein imaging tests designed to be applied to pretreatment tumor biopsies as a CDx to select and treat the patients predicted to benefit from the specific drug candidate for which they are developed. The tests are developed for routine-processed, paraffin-fixed biopsy tissue and stained with fluorescently labeled antibodies against the OncoSignature biomarkers. Digital images of these stained tissues are then processed by proprietary software that identifies both tumor cells and tumor cell nuclei. They are quantitatively measured in only defined tumor tissue regions of a patient biopsy where they function, called the "region-of-interest," or ROI. A proprietary algorithm assesses the quantitative level of each biomarker and combines them to predict the likely response to a drug or drug candidate.

The AP3 approach is designed to provide a streamlined, rationale-driven workflow to identify and validate biomarkers. Every OncoSignature test is drug-tailored. Our process to generate an OncoSignature test, including technical biomarker validation, can be completed in approximately two to three months. It measures three functionally defined classes of biomarkers that in combination are predictive of sensitivity to the particular drug. Each biomarker class can contain more than one biomarker, but we typically measure only one in each class for a total of three biomarkers. A key rationale is that patients whose tumors do not harbor the specific protein disease-driving mechanisms that are sensitive to the drug are predicted to be unlikely to respond to a particular drug or drug candidate and hence can be excluded from treatment.

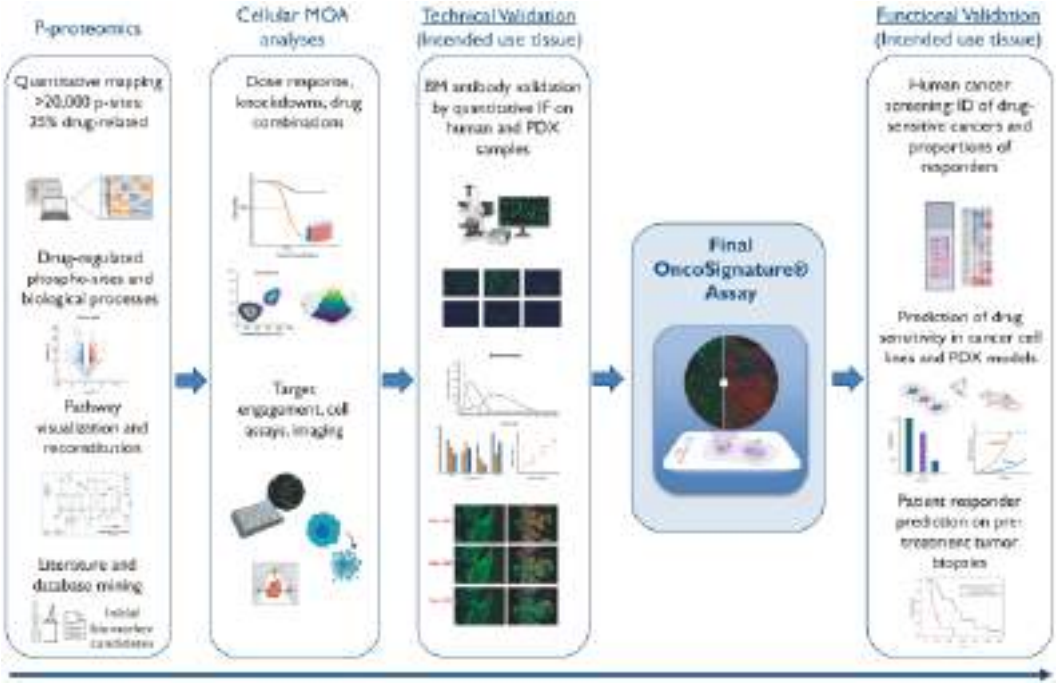

Figure 6. AP3 approach for streamlined development and validation of predictive OncoSignature tests.

In order to create an OncoSignature test that can be readily performed on clinical samples, we qualify monoclonal antibodies for the prioritized set of three biomarkers. These antibodies are chosen based on our systematic evaluation of their specificity and sensitivity including correlation in changes in biomarker levels with drug sensitivity in cell lines and, most importantly, their technical performance on human intended use FFPE-processed cancer tissues as well. This technical validation ensures specificity (that it only recognizes the biomarker of interest), dynamic range (the fold changes of the biomarker level across tumor samples), and proper intensity. The technically qualified antibodies are then assembled into a final drug-tailored predictive

OncoSignature test that is functionally validated in a blinded, prospectively designed manner in various preclinical studies. These include prediction of drug sensitivity across human tumor cell lines, in PDX models, and across human tumor samples, and, when available, on pretreatment tumor biopsies collected from past trials with the drug or drug candidate. Using our AP3 platform workflow, we have developed and evaluated in preclinical studies an OncoSignature predictive test for ACR-368, as further described below. We have also developed and done preliminary validation for two prototype OncoSignature tests for two other clinical stage assets, a CDK7 and a CDC7 inhibitor, for which genetics-based patient selection has also proven challenging.

The ACR-368 OncoSignature test will be conducted under an exclusive license with our external companion diagnostic partner, who will also commercialize the test, pending approval. The tests are performed on a standard, routine processed pre-treatment tumor biopsy with an anticipated turnaround time of five to seven business days. We intend to protect all our drug-tailored OncoSignature tests via patents for their tumor-agnostic usage across cancers.

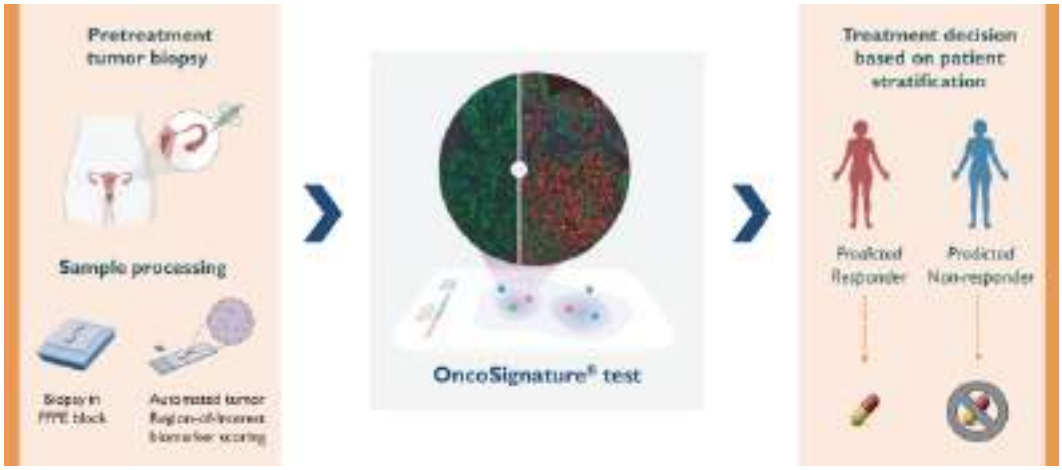

Figure 7. Our OncoSignature tests are applied to pretreatment tumor biopsies and will be offered by our CDx partner with an anticipated turn-around time of five to seven business days.

Enablement of AP3 through our team's expertise

The enablement of the AP3 approach as a means to realize the potential of proteomic drug profiling and protein signature tests in precision medicine is the result of the vision of our founders and their long-standing expertise in the field, including pioneering the underlying AP3 technologies and implementation experience. Three critical aspects behind AP3 are:

- **Founding concept and vision**. Our founders are leaders and respected authorities in the understanding of oncogenic kinase signaling, protein dysregulation through tyrosine phosphorylation, and the relationship of each to human cancer. Our vision was embedded in the 2001 *Nature* review article, "Oncogenic kinase signaling," by our founder Peter Blume-Jensen, which became a citation classic in the field of medicine. It described how cancer and other diseases are inevitably driven by dysregulated protein signaling resulting from either very simple or complex underlying genetic alterations. The paper linked simple GOF mutations in a class of proteins called tyrosine kinases with their disease-driving dysregulation and involvement in a certain small subset of human cancers. Our founding vision is that proteomic biomarkers enable direct measurement of the disease-driving mechanisms and allow for accurate matching with drug action, independent of underlying genetic alterations.
- **Technical expertise and implementation experience**. The two underlying technologies used in a stepwise manner in our AP3 platform, (1) high resolution MS for quantitative protein and protein

phosphorylation analysis and (2) the automated biomarker platform, have been pioneered and established by our founders and team and integrated into a content system and approach. Jesper Olsen, our academic co-founder, is a recognized world leader in the use of MS-based phosphoproteomics, or the study of protein phosphorylation and its impact on biology. Dr. Olsen is one of the most highly cited authors in this field. Our co-founder, Kristina Masson, has established the entire infrastructure for phosphoproteomics at our subsidiary in Medicon Village, Lund, Sweden in close proximity with Dr. Olsen's laboratory in Copenhagen, Denmark. Our OncoSignature technology is enabled by this comprehensive proteomics infrastructure and demonstrated proof-of-concept for the first unbiased MS step in the AP3 approach, resulting in identification of resistance mechanisms and rational drug combinations with the potential to be tested in controlled clinical trials with the drug selinexor in acute myeloid leukemia. This work was published in *Cell Reports* on August 9, 2022.

Peter Blume-Jensen, led the first proof-of-concept for unbiased identification of drug-regulated PD biomarkers for PI3'K pathway-targeted agents through an MS-based phosphoproteomics approach. Under his leadership, our team also led the establishment of our automated biomarker platform and the research and development of ProMark, a proteomics eight biomarker imaging test for prostate cancer outcome prediction launched by Metamark. That test was validated in a blinded trial and was subsequently included in the NCCN Clinical Practice Guidelines. Through this experience, we understand the technical and regulatory challenges involved in developing and implementing a clinically meaningful proteomic test, and we fully leverage and factor these insights into the design of our OncoSignature tests.

ACR-368, Our Phase 2 Lead Candidate

Our lead drug candidate, ACR-368, also known as prexasertib, is a selective inhibitor with sub single-digit potency against CHK1 and single-digit potency against CHK2. ACR-368 was originally discovered by Array BioPharma and acquired by Lilly, who evaluated the compound in over 1,000 patients across 18 clinical trials, where it demonstrated deep, durable single agent activity, including CRs, in a proportion of patients across several Phase 2 studies of platinum-resistant ovarian cancer and other solid tumors. Despite the demonstrated clinical activity in a proportion of patients, there was no obvious patient selection strategy to improve responses sufficient for approval. We chose to in-license ACR-368, prioritizing it over other carefully evaluated candidates, based on multiple criteria, including its proven clinical single agent activity, extensive safety data set and extensive comparison work and in-house AP3 profiling.

We have begun enrolling patients in a Phase 2 trial of ACR-368 in patients with ovarian, endometrial, or bladder cancer based on OncoSignature-predicted sensitivity to ACR-368. Akoya will procure and manufacture the necessary supplies to perform the OncoSignature tests used in the Phase 2 clinical trial. We expect to report initial clinical data from this trial during the second half of 2023. Pending results and discussions with the FDA, we intend to enter the registrational phase during 2024. Patients who test ACR-368 OncoSignature-positive will receive ACR-368 monotherapy in a single arm Phase 2 trial, while ACR-368 OncoSignature-negative patients will receive ACR-368 in combination with LDG in a Phase 1b/2 single arm trial. We also plan to study ACR-368 in additional indications, such as HPV^+ squamous cell carcinomas, including SCCHN, anal, and cervical cancer, based on demonstrated clinical single agent activity in SCCHN and anal cancer and OncoSignature-based prediction of sensitivity to ACR-368 in a proportion of patients.

ACR-368, a selective inhibitor of CHK1 and CHK2, key DDR regulators

CHK1 and CHK2 are checkpoint proteins that prevent cell replication when DNA damage is present. In the absence of DNA damage, CHK1 and CHK2 are largely inactive. Most normal tissues, other than certain dividing cells such as those in bone marrow, are not reliant on DDR mechanisms such as CHK1 and CHK2, and hence not subject to the negative side effects from such inhibitors. In contrast, inhibition of the kinase activity of these proteins or knockdown of their expression by RNA interference in certain G1/S checkpoint-deficient tumor cells has been shown to prevent repair of double-strand DNA breaks resulting in cell death. Treatment of cells with DNA damaging agents or inhibitors of other proteins involved in the DDR, sensitizes them to cell killing by CHK1 and CHK2 inhibitors.

Figure 8. CHK1 functions as a cell cycle checkpoint to inhibit DNA replication when DNA damage is present.

ACR-368 is a selective CHK1/2 inhibitor with a potency of less than 1 nM against CHK1 and 8 nM against CHK2. In preclinical studies, ACR-368 inhibited growth with a potency of less than 100 nM in over 75% of 600 cancer cell lines screened, including a potency of less than 50 nM in 16 of 23 tested ovarian cancer cell lines. ACR-368 as a single agent led to complete tumor regression in approximately 40% of 38 ovarian cancer PDX models tested. Significant anti-tumor activity was also observed in other tumor models such as sarcomas and neuroblastoma. The anti-tumor activity of ACR-368 was enhanced in preclinical models when it was combined with DNA damaging agents such as cisplatin and gemcitabine.

Clinical development of ACR-368 for patients with ovarian and other solid cancers of high unmet treatment need

We are developing ACR-368 for the treatment of patients with advanced solid tumors including ovarian, endometrial, and bladder cancers. ACR-368 has demonstrated deep, durable single agent anti-tumor clinical activity, including CRs, in a proportion of more than 400 patients treated at RP2D in past clinical trials conducted by Lilly, its previous sponsor, and in several investigator-initiated trials, including at the NCI and at MDACC. Importantly, ACR-368 was well-tolerated in these trials, exhibiting primarily reversible, manageable hematological toxicities and limited dose-limiting non-hematological toxicities. Accordingly, there have been no clinical or regulatory holds reported and less than 2% drug-related discontinuations across all trials to date. While the ORR in the single center Phase 2 study at NCI was 29%, the confirmed ORR in a 169-patient Phase 2 trial conducted in 46 centers across eight countries in platinum-resistant ovarian cancer was only approximately 12%.

By pairing ACR-368 with our compound-specific OncoSignature test, we believe we can significantly increase the ORR by targeting treatment to the patients that are predicted to be most dependent on CHK1/2, and therefore more likely to respond. Based on our preclinical studies, which include blinded, prospective studies of ACR-368 OncoSignature test on pretreatment tumor biopsies collected from patients treated with ACR-368 in the past ovarian trials, we expect 30% to 40% of patients in our three lead indications, platinum-resistant ovarian, endometrial, and bladder cancer, will be ACR-368 OncoSignature-positive. We expect the ORR to be significantly amplified and, if the data are sufficient, we will aim for single-agent, single-arm approval. These patients will be treated with ACR-368 in a Phase 2 trial at the RP2D. The remaining 60% to 70% of ACR-368 OncoSignature-negative patients will receive ACR-368 at the RP2D with LDG, which we have found to be highly synergistic with ACR-368 using our AP3 platform in preclinical studies. The IND application for our Phase 2 master protocol trial has been cleared. We have begun enrolling patients in Phase 2 clinical trials in these three tumor types and expect to report initial clinical data from this trial during the second half of 2023.

Ovarian cancer background

Ovarian cancer is the fifth deadliest cancer in women. An estimated 19,880 women in the United States are projected to be diagnosed with ovarian cancer and approximately 12,810 will die from this disease in 2022 based on projections from the NCI. The overall five-year survival rate in patients with ovarian cancer is 50% but drops to 31% in patients with metastatic disease.

Surgery and cytotoxic chemotherapies are widely used to treat patients with ovarian cancer. One of the primary chemotherapies involves the use of platinum containing regimens such as carboplatin or cisplatin. Approximately 85% to 90% of patients with ovarian cancer initially respond to these drugs, but in over 80% of cases, these cancers return and are considered platinum-resistant. For these patients, there are few remaining treatment options, including bevacizumab with chemotherapy or PARP inhibitor as maintenance therapy for some patients. Only about 12% of platinum-resistant patients achieve tumor shrinkage and, on average, people with platinum-resistant ovarian cancer survive for no longer than a year.

Endometrial cancer background

Endometrial cancer is a cancer of the lining of the uterus that primarily affects post-menopausal women. The American Cancer Society estimates that in the United States there will be 65,950 new cases of endometrial cancer and approximately 12,550 patients will die of this disease in 2022. First-line treatment for patients with localized, early-stage disease is surgery. Patients with more advanced disease, stages III or IV, are treated with chemotherapy, typically with platinum-based drugs. Approximately 60% of patients with endometrial cancer initially respond to these treatments; however, similar to ovarian cancer, resistance develops to these drugs. These platinum-resistant patients are treated with radiation therapy or may be eligible for immunotherapy treatments with lenvatinib, an angiogenesis inhibitor. Five-year survival for patients with metastatic endometrial cancer is approximately 20%.

Bladder cancer background

Bladder cancer is the most common malignancy involving the urinary system, and 90% of bladder cancer cases are urothelial carcinomas. The five-year survival for patients with early-stage disease is 96%; however, for patients with advanced metastatic disease the five-year survival drops sharply to less than 10%. The NCI estimates that there will be 81,180 new cases of bladder cancer and 17,100 deaths in the United States in 2022.

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 progress during or after platinum-based chemotherapy are increasingly being treated with immune checkpoint inhibitor therapy. A number of PD-1 and PD-L1 checkpoint inhibitors have been approved by the FDA for use in refractory bladder cancer. Objective ORRs in clinical trials with checkpoint inhibitors have been approximately 15%. On July 9, 2021, enfortumab vedotin, a nectin-4-directed antibody drug conjugate was approved for patients that have progressed after treatment with immune checkpoint inhibitors PD-1/PD-L1 and a platinum-containing chemotherapy. The ORR is about 40%, but eventually the disease progresses and the median overall survival is approximately 12 months.

Only an estimated 20% of patients with bladder cancer have alterations in the FGFR2 or FGFR3 genes. In clinical testing, erdafitinib, an FGFR-targeted drug, has demonstrated a 32% ORR with 2% of patients achieving CRs. Despite the availability of these therapies, the prognosis for patients with metastatic bladder cancer is still poor with a five-year survival rate of only 8%.

HPV$^+$ squamous cell carcinoma background

Squamous cell carcinomas are cancers that develop in the squamous cells that make up the outermost layer of the skin. More than 90% of anal cancers and cervical cancers and about 70% of SCCHN in the oropharynx, or the back of the throat, are linked to infections with HPV. There are over 46,000 HPV$^+$-associated cancers diagnosed in the United States each year and up to 5% of cancers worldwide are potentially caused by HPV$^+$ infections.

Unlike many cancers, HPV$^+$ cancers are not typically driven by high levels of genomic instability but rather by alterations in cell cycle regulation, including upregulation of DDR pathways. Certain HPV$^+$ cancers, primarily SCCHN and cervical cancer, respond to PD-1 or PD-L1 immune checkpoint inhibitor therapies with ORRs of

approximately 20%. While these and other targeted therapies are still in development for these cancers, the primary treatment is with surgery and chemotherapy regimens typically composed of a backbone of 5-fluorouracil and cisplatin, and radiation.

Sarcoma background

In addition to previously demonstrated clinical activity in the above tumor types as monotherapy, ACR-368 has also shown clinical activity in patients with sarcomas in combination with various chemotherapeutic agents. Patients with sarcomas have very limited treatment options, primarily surgery, chemotherapy, and radiation. The five-year survival for patients with metastatic soft tissue sarcomas is approximately 17%.

Previous clinical trials of ACR-368 have demonstrated compelling, durable single agent activity

ACR-368 has demonstrated deep, durable single agent activity, including CRs, in a proportion of more than 400 patients with high-grade serous, primarily platinum-resistant, ovarian cancer and SCC treated at RP2D. Overall, ACR-368 has been tested in 18 clinical trials as monotherapy or in combination with both targeted agents and chemotherapy in over 1,000 patients across primarily solid tumor types and has shown a generally favorable safety profile.

Phase 1a/b trial in squamous cell carcinoma established single agent clinical activity and the RP2D

A 146-patient Phase 1 multicenter trial was conducted in patients with refractory or recurrent squamous cell carcinoma and led by Dr. David Hong at MDACC. The trial included patients with SCCHN, sqNSCLC, and anal cancer. The primary objective of the Phase 1b expansion cohorts was to determine the safety, toxicity, and RP2D of ACR-368. In addition, the ORR according to Response Evaluation Criteria in Solid Tumors, or RECIST, version 1.1 for patients with specific types of SCC was recorded.

The RP2D was established at 105 mg/m^2 given as an intravenous infusion every 14 days, and used in the expansion phase for 101 patients. The study demonstrated clinical monotherapy activity of ACR-368, with a 5% ORR in SCCHN and 15% ORR in anal cancer. The mDoR was seven months and over 12 months, respectively, including a CR in anal cancer. Based on these results and the lack of highly effective treatments, ACR-368 has been granted FDA Orphan Drug Designation, or ODD, for the treatment of anal cancer.

Of note, approximately half of the patients with SCCHN were HPV$^+$ and showed a significantly higher ORR of 19% in response to ACR-368—a similar finding to the ORR recorded in patients with anal cancer, which is almost obligate HPV$^+$. This was reflected in a markedly longer progression-free survival, or PFS, in HPV$^+$ compared to HPV-negative, or HPV$^-$, patients, with some HPV$^+$ patients benefiting from therapy well over 12 months while no HPV$^-$ patients had benefit beyond five months (Fig. 9.).

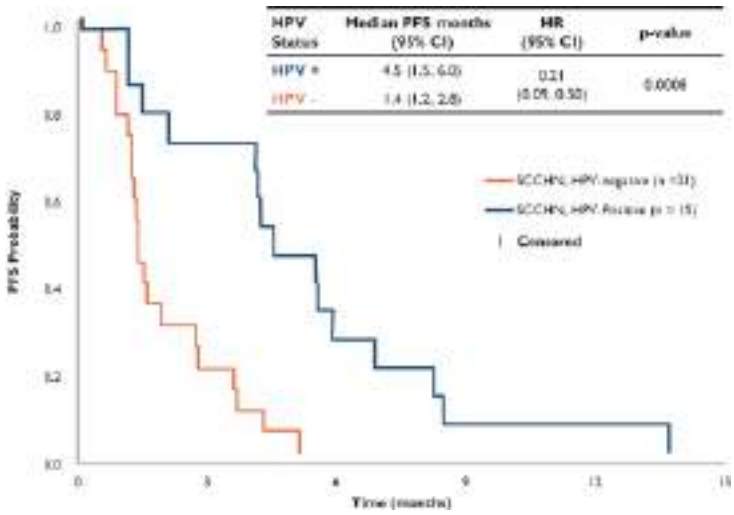

Figure 9. ACR-368 treatment resulted in a significant improvement in progression-free survival in patients with HPV^{+} SCCHN compared to patients with HPV^{-} SCCHN.

In this trial, as in most of the other clinical trials with ACR-368, an attempt was made to identify biomarkers predictive for response to ACR-368 in pretreatment tissue samples by NGS. In an analysis of genetic changes in 24 genes involved in DDR or increased replication stress, no obvious correlation with clinical response was observed. This lack of correlation between genetic changes and clinical response underscores the need for an alternative patient responder identification method, such as AP3.

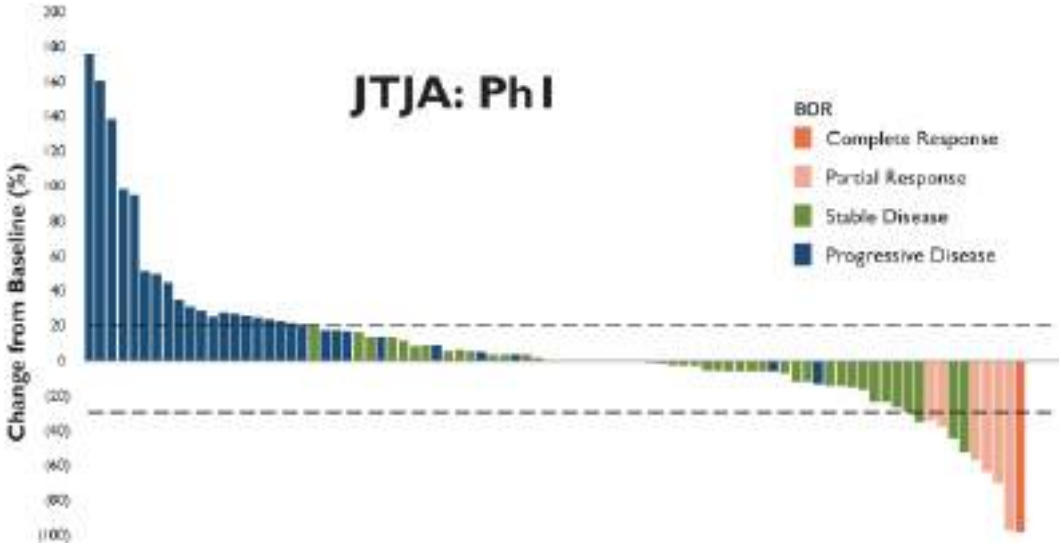

Figure 10. Maximal percentage change in tumor size from baseline by best ORR across all expansion cohorts.

Phase 2, single center NCI trial in patients with high-grade serous ovarian cancer

A Phase 2 trial of ACR-368, led by Dr. Lee at NCI, enrolled 28 women with high-grade serous ovarian cancer. ACR-368 was administered at the RP2D every 14 days until disease progression, an event of unacceptable toxicity, or withdrawal of consent. Twenty-four women had evaluable responses after three withdrew consent because of travel inconvenience and one developed an intervening illness that prevented radiological evaluation of tumor progression. All patients in this trial had failed at least one round of prior cytotoxic chemotherapy and three quarters of the patients had failed three or more prior lines of therapy. The primary endpoint in this single center trial was investigator assessed tumor response based on RECIST v1.1.

In the analysis of the ITT population of 28 patients, an ORR of 29% was achieved. For the 21 patients in the ITT population with platinum-resistant disease, an ORR of 29% was achieved. The mean duration of response in patients with platinum-resistant ovarian cancer was over ten months, with some patients remaining on ACR-368 therapy for over 16 months (Fig. 11).

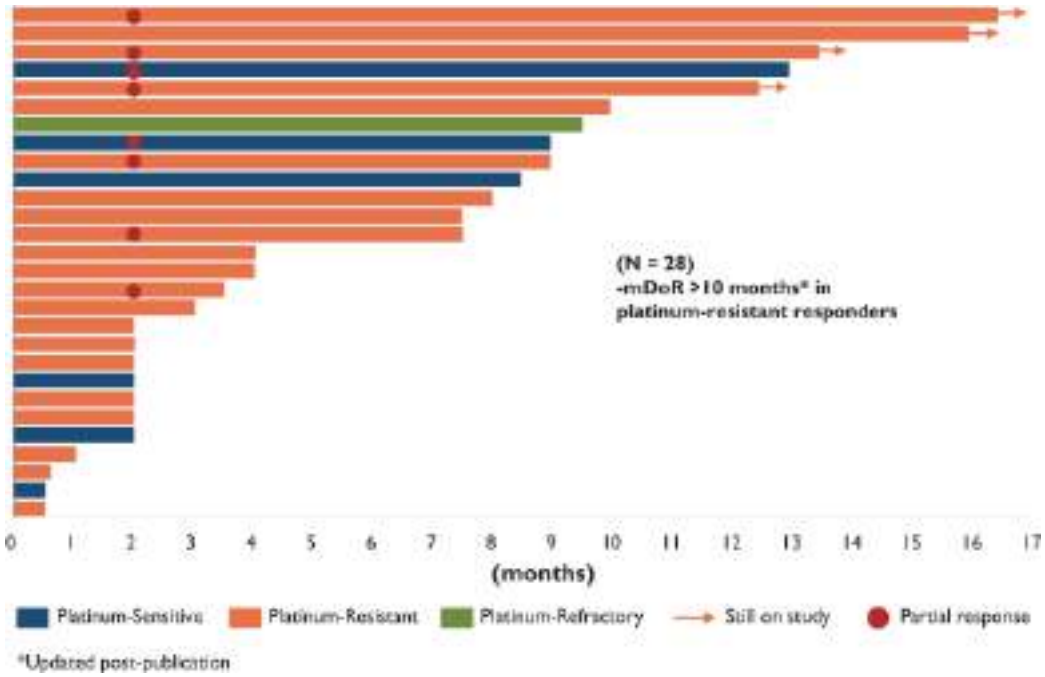

Figure 11. Duration of response with ACR-368 in a 28-patient ovarian cancer Phase 2 trial.

Similar to the findings reported for ACR-368 in SCC, there was no correlation observed between clinical response and alterations or the expression of potential biomarker genes (Fig. 12).

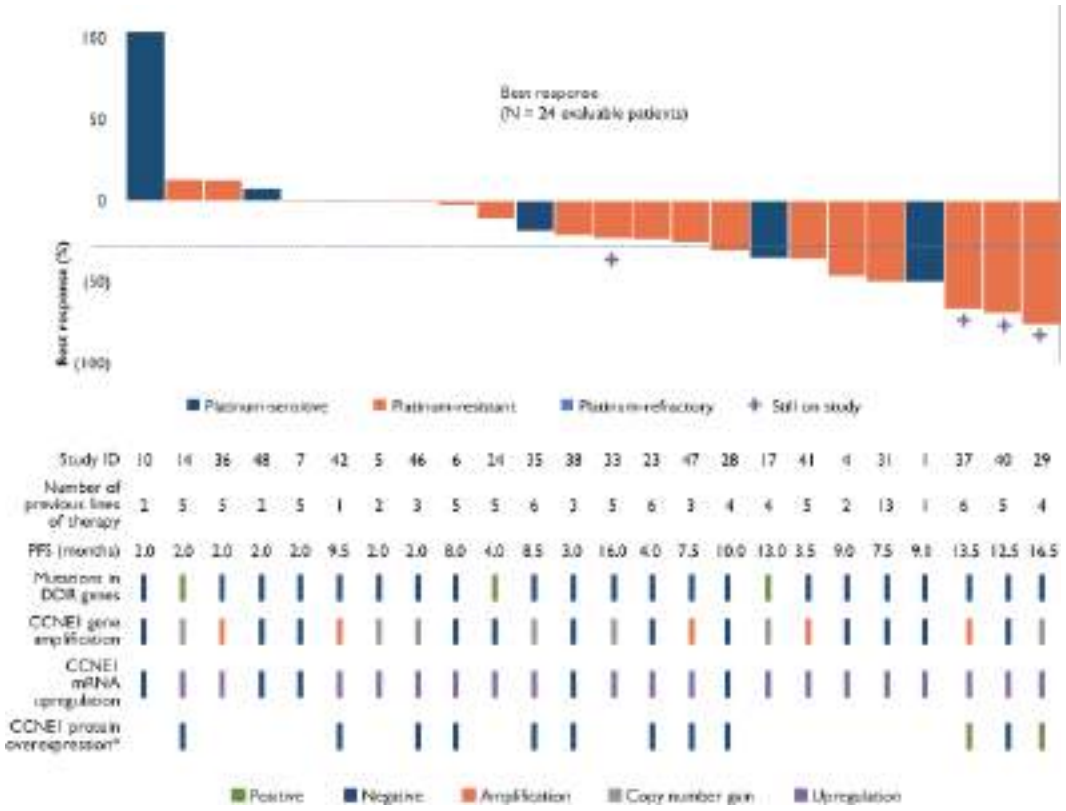

Figure 12. No correlation was observed between ACR-368 response and genetic alterations or potential biomarker expression in patients with ovarian cancer.

Phase 2 multicenter trial in advanced, high-grade serous ovarian cancer

A large Phase 2 trial of ACR-368 in patients with platinum-resistant and platinum-refractory ovarian cancer sponsored by Lilly was conducted in 46 centers across eight countries. The 169 patients enrolled in this trial had failed two to four prior systemic therapies and 90% of patients had stage III or stage IV disease. The trial included patients with either an altered BRCA1 or BRCA2 gene, or BRCA-positive, or unaltered BRCA1 or BRCA2 gene, or BRCA-negative, ovarian cancer and was divided into four cohorts.

- Cohort 1: patients with platinum-resistant, BRCA negative ovarian cancer with at least three lines of prior therapy
- Cohort 2: patients with BRCA negative platinum-resistant ovarian cancer with no more than two lines of prior therapy
- Cohort 3: patients with platinum-resistant BRCA mutant ovarian cancer with any line of prior therapy, but with obligatory prior PARP inhibitor therapy
- Cohort 4: patients with platinum-refractory BRCA negative or BRCA mutant ovarian cancer and any line of prior therapy.

N= 169 Patients	Cohort Description	Percent Confirmed ORR (95% Confidence Interval	Percent Disease Control Rate (95% Confidence Interval)
Cohort 1 (51)	Plat resistant BRCA wt ≥3 lines of prior therapy	11.3 (4.3 to 23.0)	45.3 (31.6 to 59.6)
Cohort 2 (46)	Plat resistant BRCA wt < 3 lines of prior therapy	13.0 (4.9 to 26.3)	32.6 (19.5 to 48.0)
Cohort 3 (41)	Plat resistant BRCA mt any line of therapy (must include prior PARPi)	12.2 (4.1 to 26.2)	31.7 (18.1 to 48.1)
Cohort 4 (29)	Plat refractory any BRCA any line of prior therapy	6.9 (0.8 to 23.8)	31.0 (15.3 to 50.8)

Figure 13. ORR and Disease Control Rate in each of the four cohorts of patients with platinum-resistant and platinum-refractory ovarian cancer.

The primary outcome in this study was ORR. Results from this trial showed that a subset of patients with ovarian cancer treated with ACR-368 across all four cohorts achieved durable PRs. The ORR in the 140 patients with platinum-resistant ovarian cancer was 12.1%, not including unconfirmed responders.

Secondary outcomes included Disease Control Rate, or DCR, which is the percentage of patients with a best overall response of CR, PR, or stable disease, or SD, for at least four months. The DCR was over 30% across all four cohorts, varying from 31% in patients with platinum-refractory disease to 45% in patients with platinum-resistant disease with at least three lines of prior failed therapies. In the three cohorts of patients with platinum-resistant disease, the median duration of response was 5.6 months (95% confidence interval: 3.9 months; 7.6 months), and the median duration of overall survival was 11.9 months (95% confidence interval: 9.9 months; 14 months).

Consistent with previous observations, retrospective analyses of patient pretreatment tumor samples by both NGS and by IHC failed to identify biomarkers that strongly correlated with clinical response. Despite the demonstrated clinical activity, these data underscore the need for an effective patient responder enrichment method.

ACR-368 has been generally well-tolerated with manageable side effects

There have been eight Lilly-sponsored clinical trials with ACR-368. In these trials, ACR-368 was administered to a total of 681 subjects, to 479 subjects as monotherapy and to 202 subjects in combination with other treatments. In addition, there have been 10 Investigator-Initiated Trials, or IITs, where ACR-368 was administered to a total of 283 patients as either monotherapy or in combination. The primary adverse events observed in these trials were hematological, including transient neutropenia and thrombocytopenia, both of which were generally reversible and manageable. The neutropenia and thrombocytopenia are thought to be part of the mechanism-based suppression of cells in the bone marrow, or myelosuppression, which is also seen with other DDR inhibitors. However, by dosing ACR-368 at the established RP2D once every 14 days it was found that in most patients who experienced drug-related hematologic toxicities such as neutropenia had already begun to recover by the 14th day after dosing. Hence, granulocyte colony-stimulating factor and platelet infusions to correct for neutropenia and thrombocytopenia, respectively, were not mandated but were used at the discretion of the treating physicians in these trials. Nonhematologic toxicities deemed related to ACR-368 treatment occurred at a much lower frequency and severity as summarized below, with fatigue, nausea, and diarrhea being the mostly commonly observed events. In addition, in a few patients, an association was identified between increasing ACR-368 plasma concentration following monotherapy and transient QTcF prolongation. None of these episodes led to clinical manifestations. Accordingly, drug-related discontinuations were between only 1% to 2% across all patients. A proportion of patients experienced very durable responses, and in a few cases remained on therapy for several years.

Summary of adverse events from published reports on clinical trials with ACR-368 monotherapy dosed at RP2D

Study Number NCT Number Status	Study Design Monotherapy	ACR-368 Dosing Regimen and Schedule	Number of Subjects	Summary of Safety Data*
Ovarian Carcinoma				
NCI Phase 2 single center study in platinum-resistant or refractory recurrent ovarian cancer	Single arm study in BRCA-negative, primarily platinum-resistant, recurrent high-grade serous or high-grade endometrioid ovarian carcinoma (Lee et al, Lancet Oncology, 2018)	RP2D: 105 mg/m^2 every 14 days	28 intent to treat platinum resistant (N=21), platinum-sensitive (N=6), and platinum-refractory (N=1) patients.	Most frequent treatment related AEs ≥ Grade 3: neutropenia measured at day 8, 26 (93%), leukopenia 23 (82%), thrombocytopenia 7 (25%), anemia 3 (11%), febrile neutropenia 2 (7%); most frequent treatment related non hematological AEs ≥ Grade 3: fatigue 2 (7%), vomiting 1 (4%), diarrhea 2 (7%). No deaths and no treatment discontinuation due to AEs reported. Note: in this trial, neutropenia and thrombocytopenia were measured at day 8 after infusion, which is nadir for neutropenia, to specifically assess highest degree of neutropenia, not at end of each dosing cycle, which is standard clinical practice.
Other Cancer Types				
I4D-MC-JTJA (JTJA) NCT01115790 Completed Phase 1 open-label, multicenter	Non randomized, cohort expansion in subjects advanced squamous cell carcinomas (Hong et al, Clin Cancer Res 2018)	RP2D: 105 mg/m^2 every 14 days	Total: 101 Anus: 26 H&N: 57 NSCLC: 16 + 2 subjects skin and vaginal	Most frequent treatment related AEs ≥ Grade 3: 93/101 (92%) subjects; neutropenia at day 8, 90 (89%), leukopenia 26 (26%), thrombocytopenia 16 (16%), febrile neutropenia 12 (12%), anemia 14 (14%). Most frequent treatment related non-hematological AEs ≥ Grade 3: fatigue 2 (2%), and headache 1(1%). Dose reductions in 10 subjects (10%) and dose delays in 22 (22%) due to neutropenia. No deaths and no treatment discontinuation due to AEs reported. Note: in this trial, neutropenia and thrombocytopenia were measured at day 8 after infusion, which is nadir for neutropenia, to specifically assess highest degree of neutropenia, not at end of each dosing cycle, which is standard clinical practice.
I4D-MC-JTJH (JTJH) NCT02735980 Phase 2 multicenter, nonrandomized	Parallel cohort study in subjects with extensive-Small Cell Lung Cancer who had either platinum-sensitive or platinum-resistant/refractory disease (Byers et al, Clin Lung Cancer 2021)	Cohort 1: platinum-sensitive Cohort 2: platinum-resistant/refractory RP2D: 105 mg/m^2 every 14 days	Total: 116 Cohort 1: 58 Cohort 2: 60	Treatment related AEs ≥ Grade 3: 89/116 (76.7%) subjects; neutropenia 75 (64.7%), leukopenia 30 (25.9%), thrombocytopenia 30 (25.9%), febrile neutropenia 12 (10.3%), anemia 14 (12.1%). Non-heme AEs: fatigue 5 (4.3%), and decreased appetite 2 (1.7%). Dose reductions in 8 subjects (13.3%). Dose delays in 19 (31%) due to neutropenia or thrombocytopenia, and 2 possibly drug related treatment discontinuations due to Gr3 pneumonia and Gr2 leukopenia. Mean relative dose-intensity 98.26%. Three deaths (5.4%) in cohort 1 deemed possibly related to study treatment.

* Adverse events greater than or equal to Grade 3 are considered serious adverse events

Using Our ACR-368 OncoSignature Test For Prediction of Sensitivity to ACR-368 in Our Upcoming Phase 2 Trial

Using the AP3 streamlined process as described above, we have developed a predictive OncoSignature test for ACR-368, called ACR-368 OncoSignature. We will be using this in our upcoming Phase 2 trial to treat patients with ovarian, endometrial, or bladder cancer based on predicted sensitivity to ACR-368. We have extensively evaluated our ACR-368 OncoSignature test in various preclinical studies and models demonstrating the ability to predict sensitivity to ACR-368.

Prediction of sensitivity to ACR-368 across multiple human ovarian tumor samples

Two key questions facing companies entering clinical trials is whether the chosen tumor types in a particular trial will be sensitive to the drug candidate and, if so, what percentage of patients with each of these tumor types are expected to be sensitive to the drug candidate. To acquire this important information, we use our OncoSignature tests to screen across human patient tumor samples and multiple tumor types to predict not only which tumors are sensitive to our drug candidates, but also what percentage of patients with these tumor types are predicted to respond. We have used our ACR-368 OncoSignature test in this manner to screen across commercially available human patient tumor samples and across tumors that have been routine-processed by formalin-fixation and paraffin embedding, or FFPE, just like the pretreatment tumor biopsies collected from patient tumors will be processed in our upcoming clinical trial.

Using automated image acquisition software, the biomarkers in our ACR-368 OncoSignature tests are measured quantitatively within the ROI, which is where they are informative and exert their biological function. Patient tumor samples with a minimal predictive threshold of each of the three biomarkers present predicts sensitivity to ACR-368. Conversely, patients without presence of any of the three biomarkers are predicted to not benefit from ACR-368 and will be excluded from the monotherapy arm in our upcoming clinical trials.

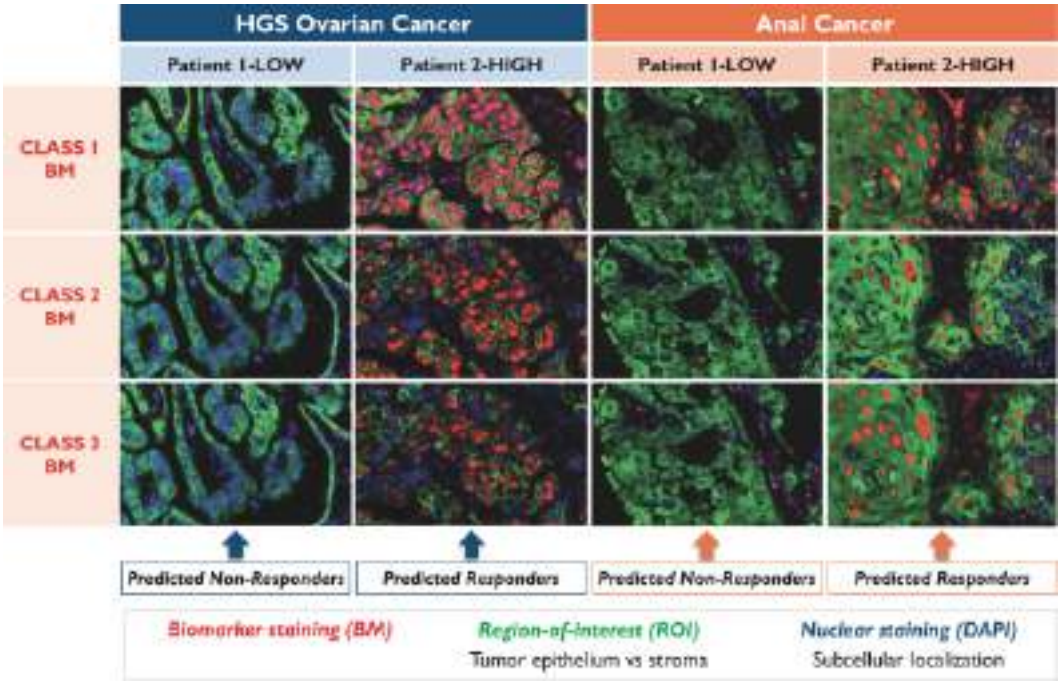

Figure 14. Screening with our ACR-368 OncoSignature across human patient tumor samples is used to predict which patients are believed to be sensitive and resistant to ACR-368, in this example using human ovarian and anal tumor samples.

Through our analysis of patient tumor samples acquired from biorepositories, we have found that in high-grade serous ovarian cancer approximately 30% of all patient tumor samples have each of the three biomarkers present above the minimal predictive threshold. This result, combined with the results described below, suggests that approximately 30% of patients could potentially benefit from treatment with ACR-368 monotherapy.

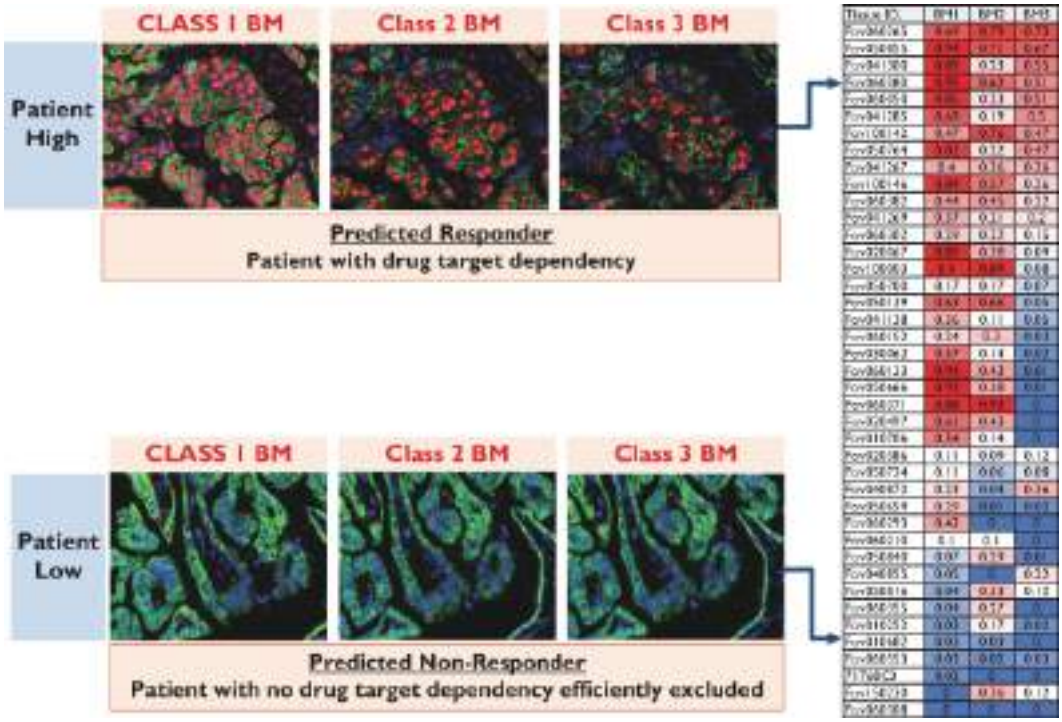

Figure 15. Our ACR-368 OncoSignature provides quantitative scores that we use to objectively predict tumor response. Patient tumor samples with all three biomarkers above a certain minimum level on the heatmap are predicted to benefit from ACR-368 therapy.

Prediction of sensitivity to ACR-368 in human tumor cell lines

Human tumor cell lines are very different from human intact tumor tissue, but are still widely used to assess anti-tumor efficacy. To date, it has been very challenging to predict sensitivity to DDR inhibitors with prevailing genetics-based methods in human tumor cell lines. However, by applying our ACR-368 OncoSignature to a small panel of human tumor cell lines, we demonstrated our ability to predict sensitivity to ACR-368 with a high degree of certainty. The presence of all three biomarkers above a minimal level predicted sensitivity to ACR-368 in all cells that are highly sensitive to ACR-368 in viability assays, except for one.

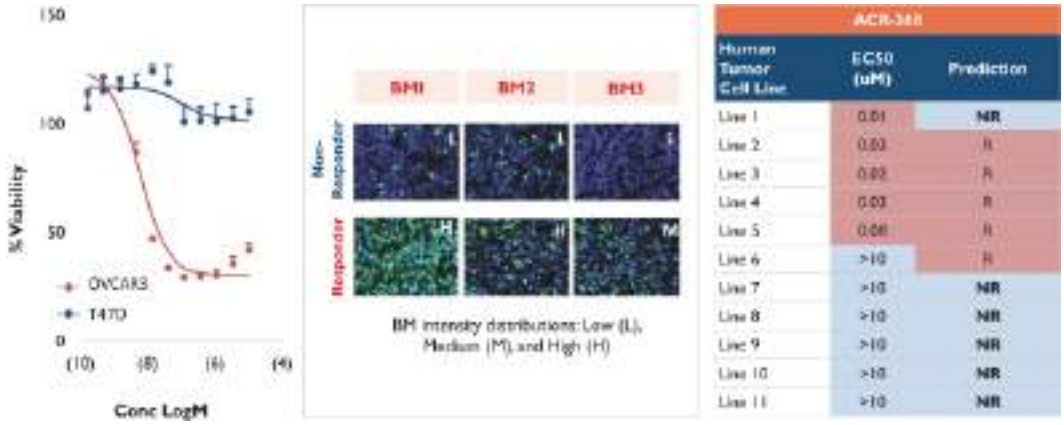

Figure 16. Prediction of ACR-368 sensitivity across human tumor cell lines.
EC_{50}: concentration of ACR-368 resulting in 50% inhibition of tumor cell survival.
R = predicted responder and NR = predicted non-responder.

Prediction of sensitivity to ACR-368 in ovarian PDX models

To demonstrate that we can also predict responders to ACR-368 in PDX models, we obtained untreated tumor tissue samples from 20 PDX models of ovarian cancer and generated quantitative biomarker scores with our ACR-368 OncoSignature test. Using the same approach, we assessed whether the tumor samples with a minimal level of each of the three biomarkers would predict sensitivity to ACR-368. We found that our ACR-368 OncoSignature was able to capture 80% of responders in PDX models while improving the ORR to approximately 55% compared to an approximated 20% baseline response rate.

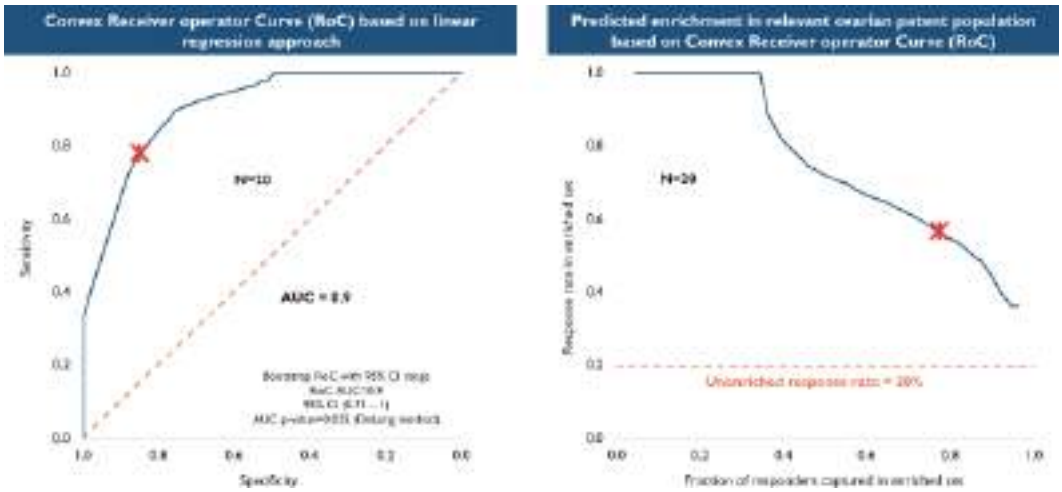

Figure 17. Our ACR-368 OncoSignature accurately distinguished responders from non-responders in PDX models; sensitivity and specificity plotted as an area under receiver operator curve, or AUC.

Blinded, prospectively designed prediction of ACR-368 sensitivity in two separate studies of pretreatment tumor biopsies from past Phase 2 trials with ACR-368 in patients with high grade serous ovarian cancer

Our OncoSignature tests are developed using only tumor cells independent of any input from clinical results. The tests are dictated by a mechanistic, functional definition of each of the three classes of biomarkers based on a strong scientific and clinical rationale as well as on our insights into biological signaling. Based on our approach, we believe we can predict that if all three classes of biomarkers are present at a minimal level in a tumor sample, the tumor depends on upregulation of the drug target signaling axis for its growth and survival. Moreover, from our phosphoproteomic drug profiling of tumor cells, we have found that this upregulated signaling axis is modulated by the drug candidate.

To test our ACR-368 OncoSignature for its ability to identify the patients that benefit from monotherapy with ACR-368, we conducted two separate studies on pretreatment tumor biopsy samples collected from patients treated with ACR-368 in past trials. Importantly, the studies were blinded to any treatment outcome annotation, the analyses were prospectively defined, and results were analyzed by an independent third-party statistician.

We were able to obtain pre-treatment biopsy samples from a subset of patients with ovarian cancer treated with ACR-368 in the prior clinical Phase 2 trials: patients treated at NCI and in the multi-center trial sponsored by Lilly. We generated OncoSignature scores on these biopsy samples blinded to treatment outcome and handed these over to the third-party biostatistician, who received the treatment outcome annotation separately. The results of both of these studies showed that use of our tumor-agnostic ACR-368 OncoSignature test was able to significantly improve the response rate, to 47% and 58%, respectively. Moreover, the results also demonstrated that a negative ACR-368 OncoSignature largely eliminated patients who are less responsive to ACR-368, hence sparing these patients from a ACR-368 single-agent treatment from which they would not benefit.

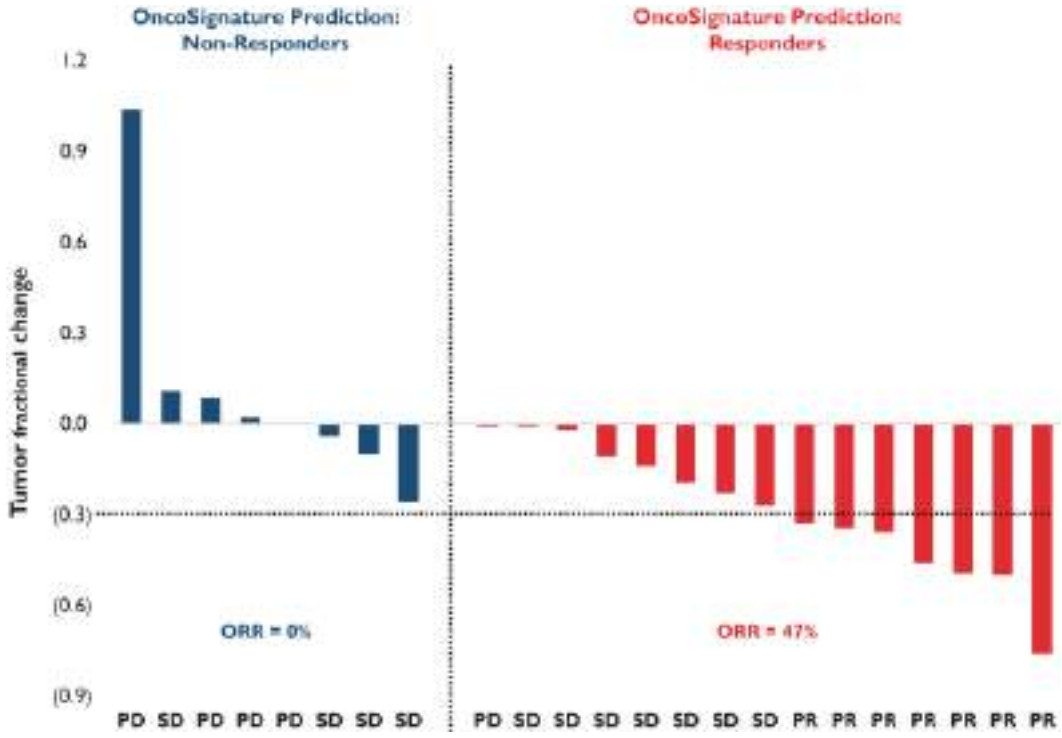

Figure 18. Blinded OncoSignature scoring of pre-treatment tumor biopsies from prior clinical trials of ACR-368 was able to segregate responders from non-responders.

Patients predicted to be sensitive to ACR-368 had a median PFS, or mPFS, of 7.9 months compared to 2.2 months for those predicted to be non-responders. This reflects the fact that not only the patients with PR or CR, but also with SD predicted by ACR-368 OncoSignature to be responders to ACR-368 treatment did indeed benefit for longer periods of time than the predicted non-responders. This could be valuable for confirmatory trials where mPFS is typically a primary endpoint.

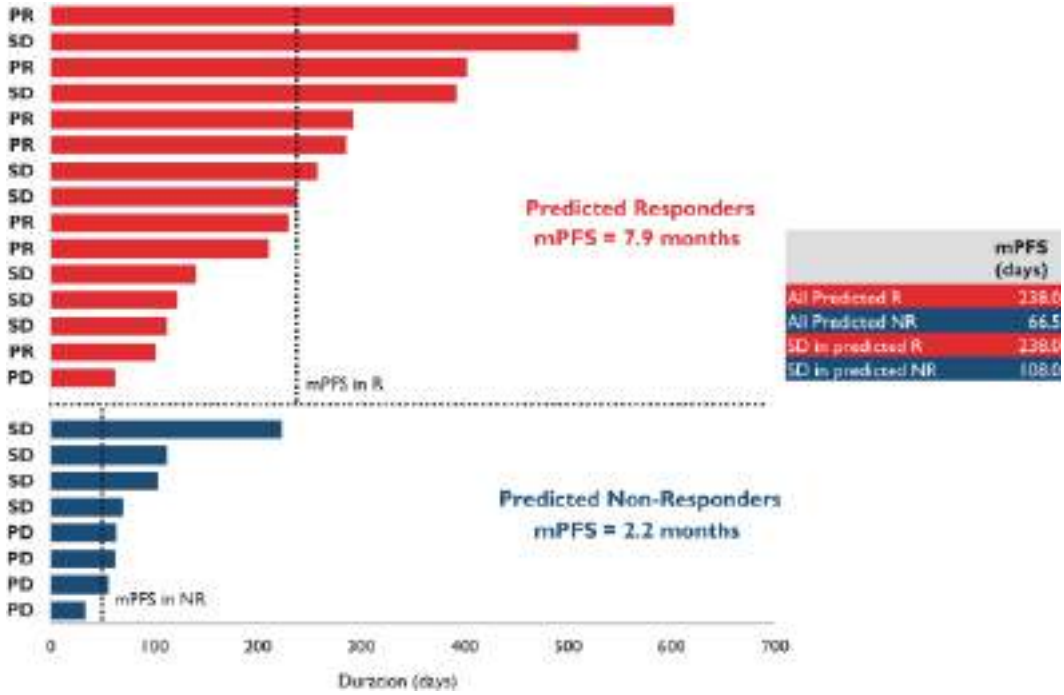

Figure 19. Patients with OncoSignature positive scores had improved PFS compared to OncoSignature negative patients.

Prediction of ACR-368 clinical activity in additional cancer indications

To identify tumor types predicted to be sensitive to ACR-368, we used our ACR-368 OncoSignature test to screen across large numbers of human patient tumor samples across tumor types obtained from biorepositories. Through this tumor-agnostic usage of ACR-368 OncoSignature we found that between 30% and 40% of samples from patients with endometrial cancer and bladder cancer were predicted to be sensitive to ACR-368. In addition to confirming the positive predictive value of our ACR-368 OncoSignature test, we have also demonstrated the high negative predictive value of our ACR-368 OncoSignature test. For example, in sqNSCLC our ACR-368 OncoSignature test predicted that none of the patient samples would be sensitive to ACR-368, which is consistent with the Phase 1 trial that was conducted in SCC types and described above, which showed an ORR of 0% in sqNSCLC. Based on these findings, which were further confirmed in PDX models of endometrial and bladder cancer, as described below, we predict that a significant proportion of patients with endometrial and bladder cancer will also be sensitive to ACR-368 monotherapy, and these two tumor types are therefore included together with ovarian cancer in our upcoming Phase 2 trial.

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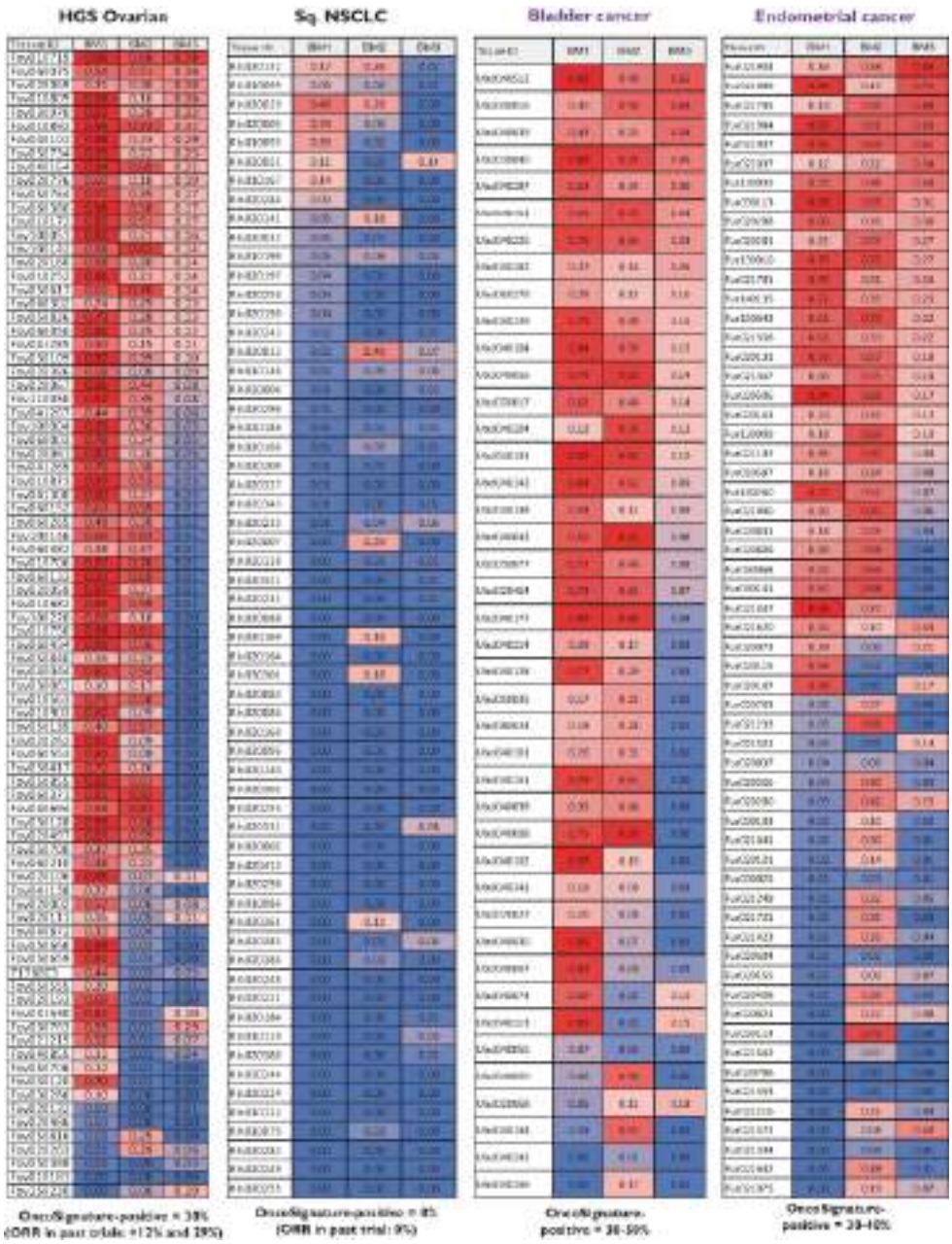

Figure 20. ACR-368 OncoSignature screening across human routine-processed FFPE patient tumor samples predicts which tumor types and what proportion thereof are sensitive to ACR-368. Each line in the four heat maps for each of the four tumor types—ovarian cancer, sqNSCLC, endometrial cancer, and bladder cancer—represents an individual tumor sample and the three columns from left to right represent the quantitative level of each of the three biomarkers in the OncoSignature test.

Confirmation of activity in PDX models of predicted tumor types

In order to confirm our prediction based on screening of human patient tumor samples that a proportion of patients with bladder and endometrial cancer are sensitive to ACR-368 monotherapy, we generated PDX models of these two tumor types and assessed anti-tumor activity of ACR-368 in these tumors. Fresh tumor tissues from mice bearing established primary human endometrial and bladder cancer tissues from 20 and 18 patients, respectively, were harvested and small pieces inoculated into mice randomized into two groups, receiving vehicle control and ACR-368, respectively, as well as a PD group used to predict ACR-368 sensitivity on the tumor tissue prior to treatment.

Mice were treated in a three-days-on, four-days-off weekly schedule for four weeks at 10 mg/kg. Mice were sacrificed either four days after last dosing or when the tumor volume in one of the arms reached 2,000 mm, whichever came first. ACR-368 demonstrated anti-tumor single agent activity in a proportion of models while others were less sensitive, consistent with the prediction obtained from screening of human patient tumor samples. This result in these preclinical studies confirmed the predicted single agent activity of ACR-368 in endometrial and bladder cancer.

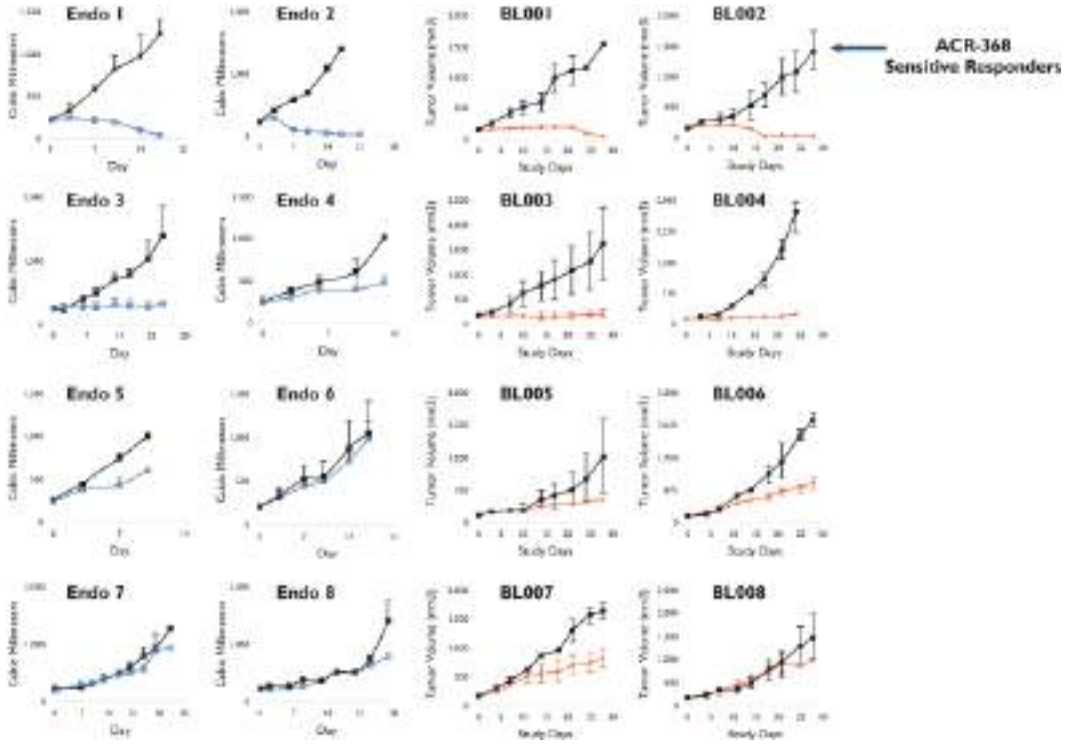

Figure 21. Assessment of anti-tumor activity of ACR-368 in PDX models of endometrial cancer (left two columns) and bladder cancer (right two columns) confirm that a proportion are sensitive to ACR-368.

Blinded, prospectively designed prediction of sensitivity to ACR-368 in endometrial PDX models

To further demonstrate the predictive power of our ACR-368 OncoSignature test, we were able to obtain de-identified FFPE tissue samples from the PD arm of the endometrial cancer PDX model study. ACR-368 OncoSignature biomarker scores were generated for 18 out of 20 PDX models, as two PDX models lacked cytokeratin expression.

Using the same minimal biomarker levels established and evaluated in all our other studies summarized above, we found that eight PDX models were ACR-368 OncoSignature-positive and predicted to be sensitive to ACR-368. After unblinding of the data and analysis by a third-party biostatistician, we showed that these models all were sensitive and experienced tumor growth inhibition, or TGI, in response to treatment with ACR-368. The ACR-368 OncoSignature-negative models, which are predicted less sensitive to ACR-368, contained all the non-responsive PDX models as well as some models with overall less pronounced TGI. The segregation of non-responders from responders was statistically significant, and a sensitivity and specificity analysis demonstrated an AUC of 0.88. Despite the well-known observation that PDX models in general tend to show a much higher percentage of responders compared to human patients, as also demonstrated in our ovarian PDX model study above, this result nevertheless confirmed the ability of our ACR-368 OncoSignature test to segregate the most sensitive from non-sensitive PDX models in a blinded, prospectively designed manner.

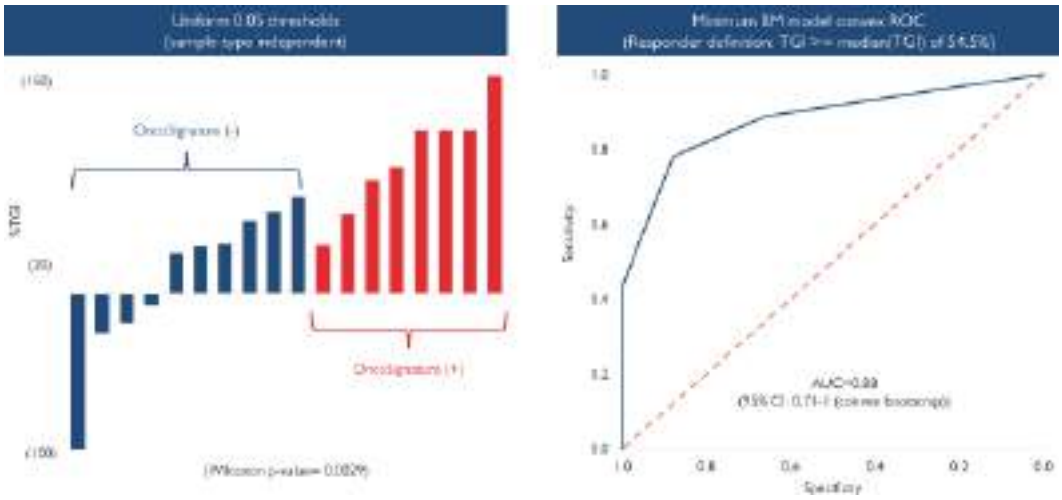

Figure 22. Blinded, prospectively designed prediction of ACR-368 sensitivity with our OncoSignature test demonstrates segregation of responders and non-responders with a p-value = 0.003 and an AUC of 0.88.

AP3 Platform Prediction of LDG as a Rational Combination to Circumvent ACR-368 Resistance

Not all tumors are sensitive to ACR-368, and those that are sensitive can develop resistance to treatment. We used our AP3 platform to identify pathways that drive resistance to ACR-368 and to propose potential combination therapies to circumvent these resistance pathways.

As an example, we generated ACR-368-resistant ovarian cancer cell lines by growing five different human tumor cell lines, including OVCAR3, that are normally sensitive to ACR-368 in the presence of a clinically relevant dose (50 nM) of ACR-368 for over ten weeks. While most cells died, a few cells developed resistance to ACR-368 and were able to grow in the presence of the drug candidate. In general, resistant cells were at least 1,000-fold less sensitive to ACR-368 than the parental cell lines. Removal of ACR-368 for up to two months in the cell lines did not alter this level of resistance, and resistance was maintained in the presence of drug efflux inhibitors, suggesting that the resistance was not due to drug efflux from the cells, but rather permanent change in cell signaling in these cell lines drove the development of resistance.

Using AP3, we conducted global proteomic analyses comparing ACR-368 sensitive and resistant OVCAR3 cells, identifying thousands of differentially expressed proteins and phosphoproteins in these cells. Pathway mapping and analyses of these proteins and phosphoproteins showed that the activity state of proteins involved in

DNA damage repair were significantly downregulated, with a compensatory upregulation of proteins involved in cell cycle progression. These changes demonstrate a low level of active DNA damage repair and hence we believe that they allowed these ACR-368 resistant cells to continue to progress through the cell cycle regardless of the presence of the drug. Furthermore, we found that cells treated with low doses of gemcitabine led to reversal of these changes, upregulating the activity of the core DNA damage repair pathways, consistent with potentially identifying a means of reversing ACR-368 resistance. This was in line with our quantitative phosphoproteomic data, which showed that treatment of ACR-368 resistant cells with LDG resulted in an upregulation of the three OncoSignature biomarkers, rendering the tumor cells more ACR-368 OncoSignature-positive after treatment with LDG.

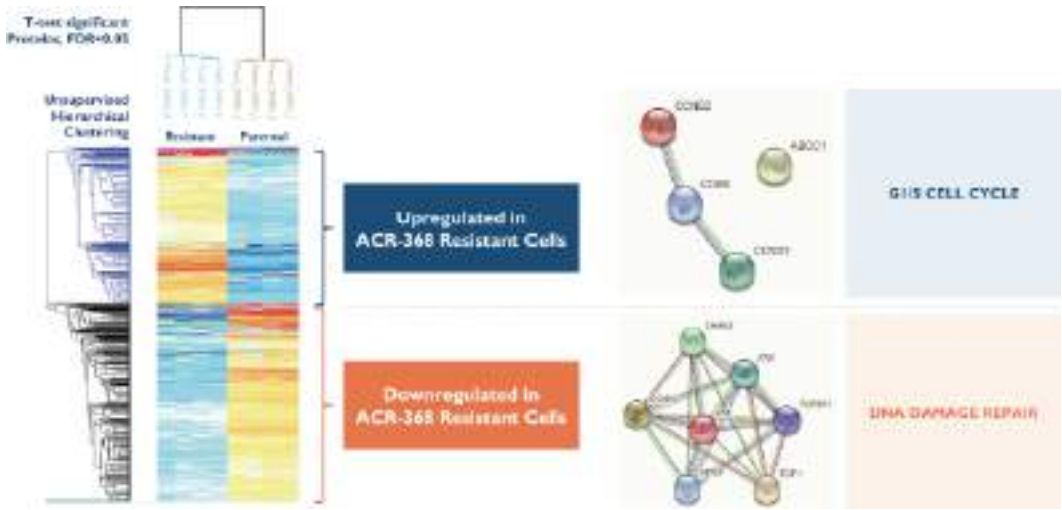

Figure 23. Proteomic analyses of ACR-368 sensitive and resistant ovarian cell lines identified activation of proteins that regulate cell cycle progression and inactivation of proteins in the DNA damage repair pathways.

These findings suggested that tumor cells that are resistant to ACR-368 should be sensitized by treatments such as gemcitabine that function by disrupting cell cycle progression. We tested this hypothesis in cell-killing assays. The five parental human ovarian tumor cell lines were highly sensitive to ACR-368 killing with a concentration required for 50% inhibition, or EC_{50} between ten to 30 nM. The EC_{50} for OVCAR3 was 15 nM ACR-368. By contrast, the resistant OVCAR3 cells had an EC_{50} of over 10 µM, which means they were over 1,000-fold less sensitive to ACR-368. Treatment of these cells with 0.53 nM gemcitabine, lowered the EC_{50} for ACR-368 to 100 nM. A further increase in gemcitabine concentration to 2.7 nM lowered the EC_{50} for ACR-368 to 6 nM. Likewise, treatment of the parental cells with the same low doses of gemcitabine increased the sensitivity to ACR-368. Treatment of these cells with 0.53 nM gemcitabine lowered the EC50 for ACR-368 to 2.7 nM. A further increase in gemcitabine concentration to 2.7 nM lowered the EC50 for ACR-368 to 0.2 nM. These findings of synergy between ACR-368 and LDG were extended into other human tumor cell lines, including endometrial and bladder.

Support for the synergistic action of ACR-368 and gemcitabine comes from the observation that gemcitabine alone does not induce potent cell death in OVCAR3 cells: at 0.53 and at 2.7 nM of gemcitabine there was no effect on cell survival, and more than half of treated cells survived at concentrations exceeding 30 µM.

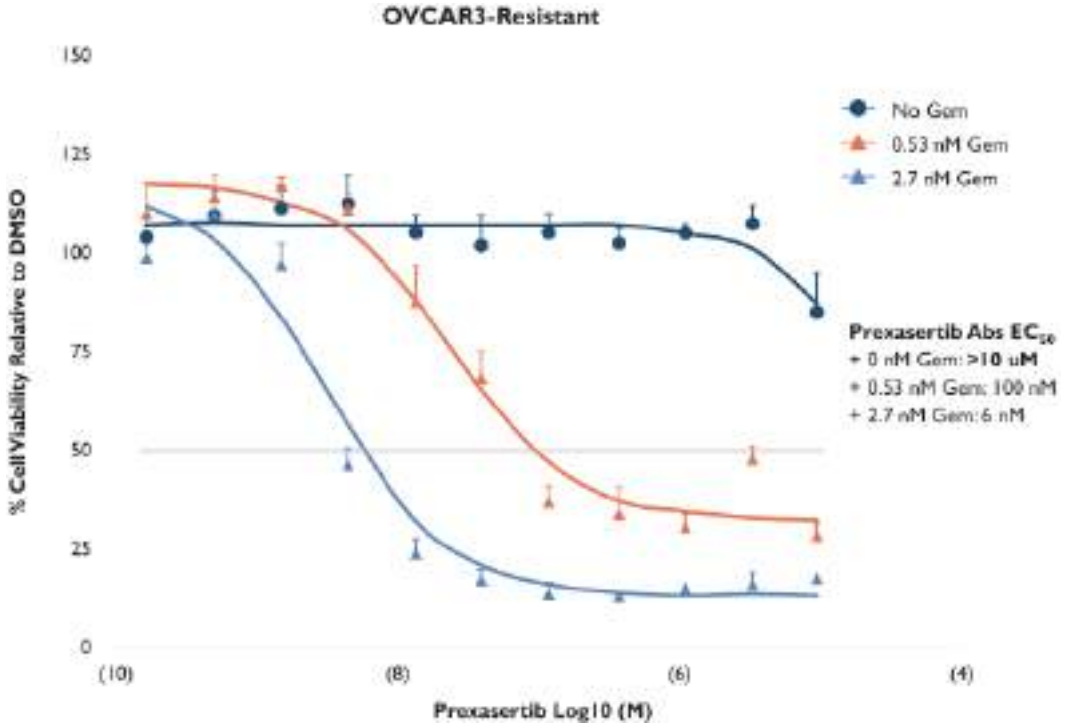

Figure 24. Low concentrations of gemcitabine sensitize a highly resistant ovarian cancer cell line to ACR-368.

Based on these results, we intend to treat patients who are predicted to be resistant to ACR-368 in our clinical trials with LDG in combination with ACR-368 to potentially overcome resistance to ACR-368.

Upcoming Phase 2 Clinical Trials of ACR-368 Based on ACR-368 OncoSignature-predicted Drug Sensitivity

The IND for our upcoming Phase 2 clinical trial of ACR-368 with cohorts of patients with advanced or metastatic recurrent platinum-resistant high-grade ovarian, endometrial, and bladder cancers has cleared. The trial will be conducted under the master protocol guidance by the FDA published in March 2022, which aims to enable expedited drug development in multiple cancer types of drugs for which the RP2D has been established in prior studies. The Phase 2 trial will be based on ACR-368 OncoSignature prediction of sensitivity to ACR-368 monotherapy on freshly sampled pretreatment tumor biopsies. Patients with ACR-368 OncoSignature-positive tumors of all three tumor types will be enrolled in an arm to be treated with ACR-368 monotherapy at RP2D in a Simon two-stage, single arm design. Patients who have OncoSignature negative tumors of all three tumor types are predicted not to be highly sensitive to ACR-368 monotherapy. These patients will be treated with ACR-368 at RP2D plus LDG in a single arm design based on our expectation that LDG will increase ACR-368 sensitivity in a proportion of these ACR-368 OncoSignature-negative patients.

In the ACR-368 OncoSignature-positive arm, up to 23 patients of each of the three tumor types will receive ACR-368 monotherapy at RP2D. Although not expected to be necessary, the trial does incorporate an opportunity to refine the OncoSignature biomarker patient selection threshold based on the first 12 patients treated with ACR-368 monotherapy. An interim futility analysis will be used to exclude the non-interesting response rate and assess the ORR. Based on this result, the study is designed to enroll up to an additional 48

patients with these tumor types with a registrational intent. The ACR-368 OncoSignature-negative patients of all three tumor types will receive ACR-368 at RP2D with increasing doses of LDG in a Phase 1b dose escalation component of the trial. Once the RP2D for LDG with ACR-368 has been found, the plan is to expand the ACR-368 OncoSignature-negative patients at the RP2D for the combination into a Phase 2 trial component for all three tumor types in a single arm design. Anti-tumor activity will be assessed by RECIST.

Figure 25. Design of the single arm Phase 2 ACR-368 monotherapy and single arm Phase 1b/2 ACR-368 with LDG combination trials.

We intend to expand our master protocol, at a later point to include patients with HPV$^+$ squamous cell carcinomas, including SCCHN, anal, and cervical cancer. The prior studies in SCCHN and anal cancer, described above, have demonstrated an unenriched ORR of 19% in patients with HPV$^+$ SCCHN, and 15% in patients with anal cancer. Moreover, the mDoR was seven months for SCCHN and above 12 months in anal cancer. The FDA has granted ODD for ACR-368 for anal cancer. Preclinical screening on human patient tumor samples suggests that approximately 25% of cases of these cancers have activated biochemical signaling pathways that are consistent with sensitivity to ACR-368. We plan to file an IND application amendment to add three additional tumor types under the same master protocol and clinical trial design described above at a later date.

Patients with additional tumor types, including sarcomas, have been observed to be sensitive to ACR-368

Several investigator-initiated trials, or IITs, have demonstrated clinical activity of ACR-368 in combination with various chemotherapeutic agents in patients with different types of sarcomas. These are of high unmet need for improved treatments, and only 17% of patients with metastatic soft tissue sarcomas survive more than five years. Importantly, these IITs have not only demonstrated clinical activity of ACR-368, but have also demonstrated that combination with chemotherapy is generally well-tolerated in these patients. For example, in a Phase 1/2 trial in patients with relapsed/refractory desmoplastic small round cell tumor and rhabdomyosarcoma conducted at Memorial Sloan Kettering Cancer Center it was reported that ACR-368 in combination with irinotecan resulted in a 32% ORR and mPFS of over 5.5 months. The combination was generally well-tolerated, leading to primarily hematological adverse events, which were manageable. We intend to initiate certain carefully selected trials in patients with sarcomas that have demonstrated promising preliminary clinical results in past trials at a later date.

Our Proprietary, Internal Preclinical Programs Targeting Critical Nodes in the DDR Pathways

We intend to leverage our AP3 platform and OncoSignature tests to aim for enrichment of patient responders for our internal preclinical programs. We strategically work on drug targets for which early-stage

clinical programs from other companies have demonstrated clinical activity or where there is a strong rationale for clinical activity, and where we believe genetics-based approaches are insufficient for patient responder identification. Our programs include WEE1 and PKMYT1. The field designing drugs that target the DDR pathway is rapidly expanding to include a number of drug candidates in development against targets such as ATR, ATM, DNA-PK, CHK1/2, and WEE1. Although several of these candidates have demonstrated anti-tumor activity in the clinic, the ORRs to treatment with these candidates have been relatively low. We believe that our AP3 platform provides us with the opportunity to not only develop OncoSignature tests to improve the response rates of existing drug candidates but can also guide the design and optimization of novel drug candidates as described above.

We are using co-crystallography-guided drug design and use of cellular drug target engagement imaging assays that incorporate insights derived from our AP3 platform, aiming to accelerate the advancement, and maximally improve the likelihood of success of, these internal programs. We are not only using our AP3 platform to generate drug-tailored, response-predictive clinical OncoSignature tests, but we also use our AP3 platform to provide unbiased, quantitative analyses of off-target effects on intracellular signaling using phosphoproteomic profiling, potentially enabling us to discover inhibitors that are both highly potent and highly selective.

In our WEE1 program, we have multiple lead compounds synthesized and co-crystallized with WEE1 at resolutions observed between 2.1 Å to 2.6 Å. As a result of these experiments, we have synthesized over 400 compounds and discovered four novel lead series. Multiple compounds have been identified with IC_{50}'s less than 10 nM. We have observed encouraging drug target engagement in cells and evaluation of their PK properties is currently underway. In parallel, we are developing a target and drug tailored OncoSignature test for patient selection.

Our second, closely related preclinical program directed at PKMYT1 is equally advanced as our WEE1 program. We have synthesized multiple lead compounds and co-crystallized these compounds with the target providing resolutions between 1.65 Å to 2.1 Å. As a result of these experiments, we have identified two novel lead series. Multiple compounds have been identified with IC_{50}'s less than 10 nM. We have also observed encouraging drug target engagement in cells and evaluation of their PK properties is currently underway. In parallel, we are developing a target and drug tailored OncoSignature test for patient selection.

We anticipate nominating a development candidate and entering IND-enabling studies for either of these programs by the end of 2023.

Expansion of Our Pipeline Through Application of AP3 and OncoSignature Tests

We have shown that our AP3 platform is capable of generating OncoSignature tests that can predict preclinical sensitivity to a number of potential cancer therapies. We are applying the power of this technology to expand our pipeline in several ways:

- Selectively pursue carefully selected in-licensing candidates for which we believe a genetics-based patient selection method is challenging and where we believe an OncoSignature predictive test can be developed that will significantly improve response rates, similar to how we identified ACR-368.
- Develop our own proprietary inhibitors of targets that we believe are highly amenable to use with an OncoSignature test. We have found that a number of DDR targets fall into this class. We have already initiated preclinical programs for two such targets.
- Establish carefully selected co-development partnerships with leading biopharmaceutical organizations that either have approved products or attractive drug candidates under competitive pressure where the availability of an OncoSignature test could significantly increase response rates, leading to new drug approvals, label expansions and the ability to deliver effective therapies to the right patients.

Broad Utility and Applications of Our AP3 Platform

Based on our extensive studies, we have demonstrated that our AP3 platform has many high impact applications, including:

- Predictive biomarkers and patient responder identification. Our AP3 platform enables identification of predictive biomarkers that are assembled into OncoSignature tests used to select patients to be treated that are predicted to be sensitive to a drug or drug candidate, so-called patient responders. This capability has been demonstrated in the studies described above. Using this approach, we have also developed predictive OncoSignature tests for a clinical stage CDK7 inhibitor and a clinical stage CDC7 inhibitor. The goal is to only treat patients most likely to benefit from the drug and avoid overtreatment of patients that do not benefit from it with the potential for side effects.
- Indication finding and expansion. The drug-tailored OncoSignature tests are also used to identify tumor types predicted to be sensitive to a drug or drug candidate. By screening across human patient tumor samples across tumor types, one can estimate the proportion of predicted responders within these samples in a matter of weeks. The goal is to identify and treat patients with attractive, high unmet need tumor types with an appropriate proportion of predicted responders and to avoid treatment of patients with tumor types that are predicted to be unresponsive to the drug or drug candidate. This is applicable to both clinical stage drug candidates and preclinical lead series. For example, through this approach we were able to identify endometrial and bladder cancer as two predicted highly ACR-368-sensitive tumor types, which are now included in our upcoming Phase 2 clinical trials. Conversely, we also found that sqNSCLC is predicted non-sensitive to the drug candidate, consistent with the clinical trial conducted by Lilly, which showed 0% ORR in their prior clinical trial in sqNSCLC. Likewise, for preclinical stage lead series, our AP3 platform enables us to know and plan for exactly which tumor types to include in any future clinical trials. This enables indication expansion and could potentially increase the response rates in clinical trials.
- Identification of resistance mechanisms. The AP3 approach is also used to identify resistance mechanisms in human cancer, preventing a desirable drug response. Resistance mechanisms can be divided into two main categories: naïve, or intrinsic, resistance and therapy-induced, or acquired, resistance. For example, we have shown that the IRS-2 adaptor protein is a key mediator of ALK-driven tumor cell survival in neuroblastoma and can serve as an intrinsic resistance mechanism to ALK inhibition. As an example of therapy-induced resistance we have shown that protein kinase C-delta, or PKC-δ, is a resistance mechanism to Notch1 inhibition in leukemia. Moreover, in studies deploying advanced MS with so-called spatial phosphoproteomics to quantify phosphopeptides with high accuracy in the nucleus and cytoplasm of cells, a method developed in co-founder Jesper Olsen's lab, we found that upregulated AKT-Foxo3 signaling and p53 loss-of-function are acquired and intrinsic resistance mechanisms to selinexor, a selective inhibitor of the nuclear export protein XPO1, in patients with AML. Understanding of resistance mechanisms is often clinically actionable, as such patients can either effectively be excluded from therapy or, as described in next paragraph, receive rational drug combinations.

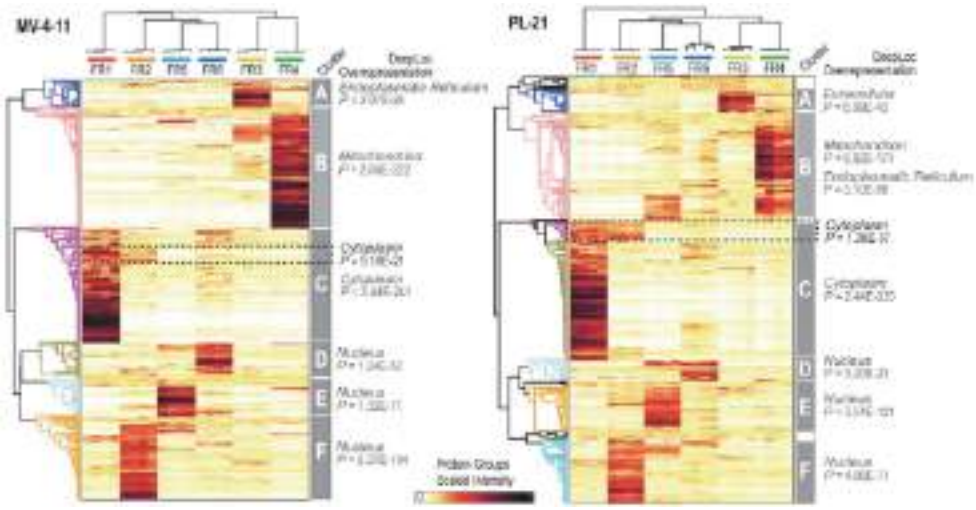

Figure 26. Spatial phosphoproteomics conducted in two human AML cell lines quantifies the nuclear and cytoplasmic levels of more than 35,000 phosphopeptides and identifies upregulated, nuclear signaling of AKT-FOXO3A as a resistance mechanism to Selinexor.

- Identification of rational drug combinations. To the extent that identified resistance mechanisms include druggable targets, these can be the basis for rational drug combinations. For example, in the studies referenced above, the uncovered resistance mechanisms included the druggable targets PKC-δ, AKT, and MDM2. Accordingly, it was demonstrated that (i) combination with the PKC inhibitor sotrastaurin overcame Notch inhibitor resistance in leukemia, (ii) combination with the AKT inhibitor MK-2206 overcame selinexor resistance, and (iii) combination with the MDM2 inhibitor, nutlin, which enhances p53 activity, enhanced selinexor sensitivity in AML. These results demonstrate the wider applicability of our AP3 platform to a number of drug target classes beyond DDR, including targets for which there is currently only limited understanding of their biological mechanisms of action.
- Unbiased drug target engagement and PD biomarker discovery. Through our high resolution phosphoproteomic drug profiling we uncover and quantify typically in the order of approximately 6,000 statistically significantly regulated phosphoproteomic changes that correlate with drug exposure. This provides a rich source of potential clinically useful biomarkers that can be developed to quantify PD drug target exposure. Such biomarkers can be used for dose-optimization through measure of the drug target engagement in patient tumor tissue in dose-finding Phase 1 clinical trials. Moreover, they can inform whether the drug candidate elicits the predicted changes in biological signaling pathways in a patient's tumor. Typically at least one of our three classes of biomarkers in our OncoSignature tests is a key PD biomarker for our drug target.

In summary, the AP3 method is broadly applicable across products and drug candidates and is developed and designed to be a transformative, efficient method to accurately match the right therapy to the right patient. Given the highly structured data resulting from AP3, we have been able to engineer it as a machine learning pipeline, aiming for high throughput and reproducible results. We expect this to be highly beneficial in our pursuit of expanding our proprietary pipeline and portfolio through continued in-licensing and co-development pharmaceutical partnerships.

Business Protection

Our AP3 platform and OncoSignature methodology has been developed and implemented for over a decade by our founding scientific team as an expert system. As such, we have multiple layers of protection. Firstly, we

have over the years established a number of tools and trade secrets that we keep as proprietary know-how in-house. Secondly, we file concrete, tumor-agnostic method-of-use patents for our drug-tailored OncoSignature tests. For example, we have filed an ACR-368 OncoSignature method-of-use patent claiming treatment of patients with ACR-368 OncoSignature-positive tumors with ACR-368 monotherapy based on predicted sensitivity to the drug. Finally, through an exclusive license arrangement with our CDx partner who will be conducting the clinical development for our test and, pending successful market approval, commercialize it, we believe we have ensured that the test cannot be offered for other DDR inhibitors.

Manufacturing

We acquired sufficient ACR-368 drug substance and drug product from Lilly to treat several hundred patients. Aside from this material, we expect to rely on, for the foreseeable future, third-party contract manufacturing organizations, or CMOs, to produce our drug candidates for preclinical studies and clinical trials, as well as for future commercial manufacture of any drugs, if approved. We require all our CMOs to conduct manufacturing activities in compliance with current good manufacturing practice, or cGMP, requirements. We have assembled a team of experienced employees and consultants who provide the necessary technical, quality and regulatory oversight to ensure the cGMP compliance of our CMOs. Currently, we have manufacturing agreements in place with three CMOs for the manufacture of ACR-368. To date we have successfully completed three familiarization campaigns, one GMP engineering campaign and three registrational campaigns for the drug substance.

We plan to continue to rely on third-party manufacturers for any future trials and commercialization, if approved, of ACR-368 and any future drug candidates. We anticipate that these CMOs will have the capacity to support commercial scale production, but do not have any formal agreements in place at this time. If needed, we believe we can identify and engage additional CMOs to provide active pharmaceutical ingredient and finished drug product without significant disruption to our business or clinical development timelines.

Licensing and Collaborations

License Agreement with Lilly

In January 2021, we entered into a license agreement and stock issuance agreement, or, collectively, the Lilly Agreement, with Lilly, pursuant to which we have been granted an exclusive, royalty-bearing sublicensable license to certain intellectual property rights owned or controlled by Lilly, to commercially develop, manufacture, use, distribute and sell therapeutic products containing the compound prexasertib.

Under the terms of the agreement, we paid Lilly an initial upfront fee payment of $5.0 million. In connection with entering into the agreement, we also entered into a common stock issuance agreement with Lilly pursuant to which we issued Lilly 336,575 shares of our common stock and 46,058 shares of Series B convertible preferred stock, which will convert into 18,677 shares of common stock immediately upon the closing of this offering. As additional consideration for the license, we are required to pay Lilly aggregate development and commercial milestone payments of up to $168.0 million, of which $5.0 million is due prior to NDA. We are also obligated to pay a tiered percentage royalty on annual net sales ranging from a low single-digit up to a maximum of 10% subject to certain specified reductions. Royalties are payable by us on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last valid claim covering the licensed product in such country, expiration of all applicable regulatory exclusivities in such country for such licensed product and the tenth anniversary of the first commercial sale of such licensed product in such country, provided, that our obligation to pay royalties for a given licensed product in a given country will expire earlier upon achievement of certain sales thresholds by generic products is such country.

We also have provided Lilly with certain, limited rights of first negotiation with us for reacquisition of the ACR-368 program with such right expiring 45 days following the completion of certain clinical milestones. The right to first negotiation expressly does not restrict any potential Change of Control transaction or IPO of our company (as each such term is contractually defined in the agreement).

Companion Diagnostic Agreement

In June 2022, we entered into a companion diagnostic agreement with Akoya pursuant to which we agreed to co-develop, validate, and commercialize our proprietary ACR-368 OncoSignature test, the CDx that will be used to identify patients with cancer most likely to respond to ACR-368.

Pursuant to the agreement, Akoya, in partnership with us, will develop, clinically validate, seek regulatory approval for, and, pending ACR-368 approval, commercialize the OncoSignature test required for prescribing ACR-368. Development of the CDx will be overseen by a joint steering committee. Each party is required to use commercially reasonable efforts to carry out its activities under the agreement. The agreement contains certain mutual exclusivity obligations of the parties with respect to the biomarkers and drug target, subject to certain specified limitations, including in the event that Akoya is unable to sufficiently supply commercial needs of such CDx.

Pursuant to the agreement, we paid Akoya a one-time, non-refundable, non-creditable upfront payment in the amount of $0.6 million. The Company is obligated to pay Akoya up to an aggregate of $10.3 million upon the achievement of specified development milestones. As of October 17, 2022, development milestones have been achieved under the agreement, resulting in payments of $2.3 million by the Company to Akoya. Other than certain specified pass-through costs, each party is responsible for its own costs associated with the development of the companion diagnostic. Akoya will procure and manufacture necessary supplies to perform the ACR-368 OncoSignature test to support our clinical development and commercial requirements, in accordance with a supply agreement to be mutually agreed upon by the parties. We may terminate the agreement at our convenience, subject to the payment of a termination fee in the amount of $1.0 million.

The agreement shall, unless terminated early, continue in perpetuity. Either party may terminate the agreement in the event of an uncured, material breach by the other party or insolvency of the other party. Additionally, we may terminate the agreement for any reason subject to a specified notice period.

Patent License Agreement

In April 2018, we entered into a patent license agreement, or the Blume-Jensen License Agreement, with Peter Blume-Jensen, our Chief Executive Officer and President, that granted us an exclusive, worldwide, irrevocable, perpetual, royalty-free license under certain licensed patents relating to broad aspects of the general discovery process for biomarkers in our drug-tailored OncoSignature tests, such as our ACR-368 OncoSignature test, for any and all purposes and uses, including without limitation and rights to sublicense through multiple tiers.

Under the terms of the Blume-Jensen License Agreement, we issued 871,857 shares of our common stock to Dr. Blume-Jensen. In addition, we were obligated to reimburse Dr. Blume-Jensen the sum of $150,000, which represented the parties' agreed upon estimate of unreimbursed past expenses incurred by Dr. Blume-Jensen with respect to the preparation, filing, prosecution, protection and maintenance of the licensed patents, within 30 days following the closing of an equity financing by us with gross proceeds of at least $2,000,000. Following the closing of our Series A-1 Preferred Stock financing, we paid Dr. Blume-Jensen $150,000 in October 2020 to satisfy this obligation.

Unless otherwise terminated pursuant to its termination provisions, the Blume-Jensen License Agreement will expire upon the expiration of all claims under the licensed patents. We have the right to terminate the Blume-Jensen License Agreement at any time upon written notice to Dr. Blume-Jensen. Dr. Blume-Jensen may also terminate the Blume-Jensen License Agreement in the event of our dissolution, liquidation, bankruptcy or if we cease operations for a continuous period of 12 months.

Intellectual Property

We pursue a layered intellectual property strategy, including patents, trademarks, and trade secret rights, to protect our AP3 platform, the OncoSignature tests we develop with it, and the drug candidates we work to commercialize.

Given the early stage of development of our drug candidates, we cannot be certain that any of our intellectual property rights will provide protection for any drug candidate that may ultimately be commercialized. ACR-368 is our only drug candidate that has advanced to clinical testing, and there can be no certainty that its clinical development will be successful, or that significant modification or adjustment will not be required for successful commercialization.

Our future commercial success depends, in part, on our abilities to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; to defend and enforce our patents and other intellectual property; to preserve the confidentiality of our trade secrets; and to operate without infringing, misappropriating or violating the valid and enforceable patents and other intellectual property rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products, or from developing competing diagnostic technologies, may depend on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities. We cannot be sure that patents will issue with respect to any of the owned or licensed pending patent applications or, with respect to any patent applications that we may file or license in the future, nor can we be sure that any of our owned or licensed patents or any patents that may be issued now or in the future will be commercially useful in protecting any products that we ultimately attempt to commercialize, or any method of making or using such products. Moreover, we may be unable to obtain patent protection for certain of our drug candidates, or for our OncoSignature tests or AP3 platform. See the section titled “Risk Factors—Risks Related to Intellectual Property” for a more comprehensive description of risks related to our intellectual property.

Patents

An issued patent provides its owner (or its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the “term” of the patent), in the jurisdiction in which the patent is issued. In the United States, and in many other countries, patents have a presumptive term of 20 years from their effective filing date (which is the earliest non-provisional filing date to which the patent claims priority). However, many jurisdictions, including the United States, require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term; some jurisdictions require periodic annuities to be paid even to maintain pendency of an application. The United States also has provisions that require a patent term to be shortened if its claims are too similar to another patent owned by the same party that has a shorter term. The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that claim a drug or drug product, or its approved use, if the patent was issued before clinical trials were completed and certain other requirements were satisfied. In the United States, such extension is called a Patent Term Extension, or PTE, and it is limited to a period of not more than five years, or a period that would extend the patent so that the total patent term including the PTE does not exceed 14 years after the date of regulatory approval; only one patent can be extended per product approval. The United States also offers a different form of patent term extension, known as Patent Term Adjustment, or PTA, whereby a particular patent’s term is automatically extended beyond the 20-year date if the United States Patent and Trademark Office, or the USPTO, caused delay during its examination; however, potentially available PTA is reduced by any amount of any delay caused by the patent applicant.

Our patent portfolio includes both in-licensed and owned patent filings, as discussed in more detail below. Particularly given our pre-commercial state of development, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for any drug or OncoSignature test we ultimately attempt to commercialize.

We have in-licensed from Lilly a portfolio including three families of patent filings relating to ACR-368. See the section titled "Business—Licensing and Collaborations." The first family, with a presumptive twenty-year term extending into 2029, includes issued patents in the United States (US patent 8,314,108, which, due to PTA, will expire in 2030) and including in Europe, China, Hong Kong, Japan, Macao and Taiwan. The second family, with a presumptive twenty-year term extending into 2036, includes issued patents in the United States (US patent 11,123,326, which, due to PTA, will expire in 2037) and in Europe, Japan and Taiwan and a pending application in the United States, that claim use of ACR-368 to treat certain particular types of cancer. The third family, with a presumptive twenty-year term extending into late 2036, includes issued patents in the United States (US patent 10,189,818, which, due to PTA, will expire in 2037) and in Europe, China, Hong Kong, Japan and Taiwan. We may be able to pursue patent term extension in one or more jurisdictions for patents in this in-licensed portfolio to provide extended protection to ACR-368.

We have also in-licensed from our founder a patent family with a presumptive twenty-year term extending into 2028 that includes issued EP and pending US filings that claims aspects of our AP3 platform relating to methods of identifying responder populations.

We own a provisional patent filing in the United States directed to our OncoSignature test for ACR-368, including claims to methods of treating patients identified by the OncoSignature test with ACR-368; non-provisional filings in the United States that claim the benefit of this filing and filings in other jurisdictions that claim priority to this filing would have a presumptive twenty-year term extending into 2043.

We intend to pursue patent protection, whether through in-licensing or our own development, for future drug candidates and OncoSignature tests. We may also pursue additional patent protection for features of our AP3 platform, though we will rely on confidentiality and trade secret protections for certain aspects of that platform.

Trademarks

We have registered our rights in the OncoSignature mark in the United States and various other jurisdictions. We expect to pursue trademark protection for additional marks in the future for products and assays that we commercialize.

Trade Secrets and Confidential Information

For certain of our technologies, including aspects of our AP3 platform and how we use it to develop OncoSignature tests, we rely on unpatented trade secrets and confidential know-how to develop and maintain our competitive position. However, trade secrets are notoriously difficult to protect. Breaches of trade secret or confidentiality provisions can be challenging to detect, and even more challenging to prove. We seek to protect our proprietary information, in part, through confidentiality and non-competition agreements with employees, consultants, partners, and other advisors. These agreements may be breached and we may not be able to successfully defend our rights. Moreover, we may not be able to secure adequate remedies for harm caused by such breach. Furthermore, our trade secrets or confidential information may be independently developed by a third party, and we may not have any ability to restrain or secure any remedy from them. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. See the section titled "Risk Factors—Risks Related to Intellectual Property" for a more comprehensive description of risks related to our trade secrets and confidential information.

Competition

The biopharmaceutical industry is characterized by the rapid evolution of technologies and understanding of precision medicine in oncology, intense competition and a strong emphasis on intellectual property. As one of the first companies to adopt a phosphoproteomics-based approach with a platform designed to develop predictive

protein signature tests for patient responder identification, we believe that our differentiated approach, strategy, as well as our scientific capabilities, know-how and experience provide us with significant competitive advantages. However, in the future, we expect competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

At present, we do not believe we face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of targeted oncology therapies for the smaller subsets of patients with genetically-defined cancers. However, we anticipate several biopharmaceutical companies will aim to develop precision oncology approaches for the larger subsets of cancers where genetics has proven insufficient for patient responder identification. We expect that the broader biopharmaceutical field will eventually recognize proteomics as the next era of precision medicine, but we believe it will take some time before significant competition will truly emerge in this space. There are several competitors with CHK1/2 inhibitors and WEE1 inhibitors, including Sierra Oncology (SRA737), Astrazeneca/Merck (Adavosertib), Zentalis (Zn-c3), Debiopharm (Debio0123), Impact Therapeutics (IMP7068) and Shouya Holdings (SY-4835).

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

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable label than our drug candidates. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical and diagnostic products. These agencies and other federal, state and local entities regulate research and

development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of drug and diagnostic products.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve a pending New Drug Application, or NDA, withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, debarment, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- nonclinical laboratory and animal tests that must be conducted in accordance with applicable regulations, including good laboratory practices, or GLPs;
- submission to the FDA of an investigational new drug, or IND, application, which must become effective before clinical trials may begin;
- approval by an independent institutional review board, or IRB, for each clinical site or centrally before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended use, performed in accordance with good clinical practices, or GCPs;
- submission to the FDA of an NDA and payment of user fees;
- satisfactory completion of an FDA advisory committee review, if applicable;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMPs and GCPs;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA review and approval of an NDA to permit commercial marketing for particular indications for use; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

The testing and approval process requires substantial time, effort and financial resources.

Preclinical Studies

Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a drug candidate, a sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or

literature, among other required information, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial 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. The FDA also may impose a partial clinical hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each institution participating in the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial commences at that site. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans.

Regulatory authorities, an 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, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, or if the drug has been associated with unexpected serious harm to subjects. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise the sponsor to 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.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

Phase 1. Studies are initially conducted to test the drug candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. If possible, Phase 1 clinical trials may also be used to gain early evidence of product effectiveness.

Phase 2. Controlled studies are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expansive Phase 3 clinical trials.

Phase 3. These clinical trials are generally undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These clinical trials may be done at trial sites outside the United States as long as the global sites are also representative of the U.S. population and the conduct of the study at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a drug candidate and can provide important safety information.

We intend to proceed with the design and conduct of certain of our clinical trials under the FDA's master protocol guidance. This guidance is intended to provide recommendations to sponsors of drugs or biologics for the treatment of cancer to expedite the development of such products by simultaneously evaluating more than one investigational drug and/or more than one cancer type within the same overall trial structure (master protocols) in adult and pediatric cancers. In general, the RP2D should have been established for an investigational drug or drugs evaluated in a master protocol.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the study by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Information about some clinical trials, including a description of the trial and trial results, must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events occur.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

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

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval, and priority review, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Under the fast track program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat patients with a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides additional opportunities for interaction with the FDA's review team and may allow for rolling review of NDA components before the completed application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. The FDA may decide to rescind the fast track designation if it determines that the qualifying criteria no longer apply.

In addition, a sponsor can request breakthrough therapy designation for a drug if it is intended, alone or in combination with one or more other drugs, to treat patients with a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for intensive guidance from the FDA on an efficient drug development program, organizational commitment to the development and review of the product including involvement of senior managers, and, like fast track products, are also eligible for rolling review of the NDA. Both fast track and breakthrough therapy products may be eligible for accelerated approval and/or priority review, if relevant criteria are met.

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. A drug candidate approved on this basis is subject to rigorous post marketing compliance requirements, including the completion of Phase 4 or post approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post approval studies, or confirm a clinical benefit during post marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period.

Once an NDA is submitted for a product intended to treat patients with a serious condition, the FDA may assign a priority review designation if the FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act, or PDUFA, guidelines. Under the current PDUFA performance goals, these six and ten month review periods are measured from the 60-day filing date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review from the date of submission. In addition, the FDA may review applications under Real-Time Oncology Review, or RTOR, which, according to the FDA, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under RTOR must be likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted breakthrough therapy designation for the same or other indications, and must have straightforward study designs and endpoints that can be easily interpreted. RTOR allows the FDA to review much of the data in a NDA earlier, before the applicant formally submits the complete application. This analysis of the pre-submission package gives the FDA and applicants an early opportunity to address data quality and potential review issues and allows the FDA to provide early feedback regarding the most effective way to analyze data to properly address key regulatory questions.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, the manufacturer of an investigational drug for a serious or life threatening disease is required to make available, such as by posting on its website, its policy on responding to requests for expanded access. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients, that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary of the reasons for not referring it to an advisory committee. The FDA may also refer drugs which present difficult questions of safety or efficacy to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA 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, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has set the review goal of 10 months from the 60-day filing date to complete its initial review of a standard NDA for a new molecular entity, or NME, and make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding the submission during the review period that amends the original application.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter, or CRL, or an approval letter. A CRL indicates that the review cycle of the application is complete and the

application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information or analyses in order for the FDA to reconsider the application in the future. Even with the submission of 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 may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a REMS as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product, or impose additional post-marketing requirements, 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, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, which has resulted in a boxed warning. A boxed warning is the strictest warning put in the labeling of prescription drugs or drug products by the FDA when there is reasonable evidence of an association of a serious hazard with the drug. The FDA also may not approve the inclusion of all labeling claims sought by an applicant. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

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

If a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA, to market the same drug 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 holder of the orphan drug exclusivity cannot 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 Orphan Drug Designation are tax credits for certain research and a waiver of the NDA application 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 orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

U.S. Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program fee requirements for approved products, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications, and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

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 withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are consistent with the FDA approved labeling. Physicians, in their independent professional medical judgment, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. However, manufacturers and third parties acting on their behalf are prohibited from marketing or promoting drugs in a manner inconsistent with the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal

and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. It is also possible that failure to comply with the FDA's requirements relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Any of these sanctions could result in adverse publicity, among other adverse consequences.

U.S. Marketing Exclusivity

The FDA provides periods of non-patent regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to new chemical entities, or NCEs. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

Regulation of Companion Diagnostics

We believe that the success of ACR-368 and certain of our drug candidates may depend, in part, on the development and commercialization of OncoSignature, a companion diagnostic candidate. Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and approval of a premarket, or PMA approval. We intend to seek PMA approval of our OncoSignature companion diagnostic candidate.

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

the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

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

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

Regulation Outside the United States

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Other Healthcare Laws and Compliance Requirements

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education and other activities are subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including the Department of Justice, the Department of Health and Human Services, or HHS, and its various divisions, including Centers for Medicare & Medicaid Services, or CMS, and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense and state and local governments. Our business activities must comply with numerous healthcare laws and regulations, including those described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable under

Medicare, Medicaid or other federal healthcare programs. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, amended the intent requirement of the federal Anti-Kickback Statute, and other healthcare criminal fraud statutes, so that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it, to have violated the statute. The ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, or FCA.

The federal civil and criminal false claims laws, including the FCA, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the U.S. federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for “off-label” uses; and submitting inflated best price information to the Medicaid Rebate Program.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibits, among other things, 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 whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of some of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

Additionally, the federal Open Payments program pursuant to the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with specified exceptions) to report annually information related to

specified payments or other transfers of value provided to physicians, as defined by such law, certain other healthcare providers (such as physician assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also 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.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, state and local laws that require the registration of pharmaceutical sales representatives, 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 may not have the same effect, thus complicating compliance efforts.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, 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, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Coverage and Reimbursement

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for the procedures utilizing our drug candidates, performed by health care providers, once approved, will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which procedures, and the products utilized in such procedures, they will cover and establish reimbursement levels. Assuming coverage is obtained for procedures utilizing a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate

or may require co-payments that patients find unacceptably high. Patients who undergo procedures for the treatment of their conditions, and their treating physicians, generally rely on third-party payors to reimburse all or part of the costs associated with the procedures which utilize our products. Treating physicians are unlikely to use and order our products unless coverage is provided and the reimbursement is adequate to cover all or a significant portion of the cost of the procedures which utilize our products. Therefore, coverage and adequate reimbursement for procedures which utilize new products is critical to the acceptance of such new products. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of cost containment, such as including price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products and procedures. Government and other third-party payors are increasingly challenging the prices charged for health care products and procedures, examining the cost effectiveness of procedures, and the products used in such procedures, in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement. Further, no uniform policy requirement for coverage and reimbursement exists among third-party payors in the United States, which causes significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and the procedures which may utilize such newly approved products. Therefore, coverage and reimbursement can differ significantly from payor to payor and health care provider to health care provider. As a result, the coverage determination process is often a time-consuming and costly process that requires the provision of scientific and clinical support for the use of new products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Additionally, we may develop, either by ourselves or with collaborators, companion diagnostic tests for our lead drug candidate for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our drug candidates, if approved. While we have not yet developed any companion diagnostic test for our drug candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons that are applicable to our drug candidates.

There may also be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product, or the procedures which utilize such product, will be paid for in all cases or at a rate which the health care providers who purchase those products will find cost effective. Additionally, we expect pricing pressures in connection with the sale of any of our drug candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes.

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize, or the procedures which utilize such product, and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any drug candidate for which we obtain marketing approval.

Healthcare Reform

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

efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

By way of example, in March 2010, the ACA was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the BBA and the Infrastructure Investment and Jobs Act, will remain in effect until 2031 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics, also has resulted in executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering drug pricing and other health reform initiatives.

At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies.

We expect that these initiatives, as well as other healthcare reform measures that may be adopted in the future, as well as the trend toward managed healthcare and increasing influence of managed care organizations, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. It is also possible that additional governmental action is taken

in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize our drug candidates.

Data Privacy and Security

In the ordinary course of our business, we collect, process and store confidential and sensitive information, including personal information, intellectual property, trade secrets, and proprietary information owned or controlled by ourselves or other third parties. We, and third parties upon whom we rely, use sophisticated information technology, software and services to process, store, use, generate, transfer and disclose information, as well as other sensitive information controlled by ourselves or other third parties.

We may also be subject to federal, state, and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including 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 FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners, vendors, or other third parties on whom we rely. The legislative and regulatory framework related to the collection, use, retention, safeguarding, disclosure, sharing, transfer, security and other processing of personal data worldwide is rapidly evolving. The number and scope of data protection laws and regulations is changing, subject to differing applications and interpretations, and may be inconsistent among jurisdictions, or in conflict with other rules, laws or other data processing obligations. Efforts to ensure that our current and future business arrangements, including our relationship with our CROs or other vendors who process data on our behalf, comply with applicable data privacy and data security laws and regulations will involve substantial costs.

For example, HIPAA, as amended by HITECH, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health plans and health care clearinghouses, known as covered entities, as well as their business associates and covered subcontractors that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that 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 may be subject to civil and criminal penalties. Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018 (CCPA), which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States. Although the CCPA exempts certain data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to the personal information we maintain about California residents. The CCPA among other effects, creates individual privacy rights for California consumers (as defined in the law), places

increased privacy and security obligations on entities handling certain personal data of consumers or households, requires covered companies to provide disclosures to consumers regarding data collection, use and sharing practices, requires covered companies to allow users to opt-out of certain sales or transfers of personal information, and provides consumers with a private right of action for certain data breaches. The CCPA became effective on January 1, 2020, and the California Attorney General's authority to begin bringing enforcement actions began July 1, 2020. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Further, the California Privacy Rights Act (CPRA) was recently voted into law by California residents. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect on January 1, 2023, and become enforceable on July 1, 2023. A similar law, the Consumer Data Protection Act (CDPA), was recently passed in Virginia and goes into effect on January 1, 2023.

We also are or will become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in the EU, we are subject to Regulation (EU) 2016/679, the GDPR, in relation to our collection, control, processing, and other use of personal data (i.e. data relating to an identified or identifiable living individual). We process personal data in relation to participants in our clinical trials in the European Economic Area (EEA), including the health and medical information of these participants. The GDPR is directly applicable in each EU and EEA Member State, however, it provides that EU and EEA Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. As noted above, the GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to EEA rules with respect to cross-border transfers of personal data out of the EEA. As noted above, recent legal developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States, e.g. on July 16, 2020, the Court of Justice of the European Union (CJEU), invalidated the EU-U.S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses 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. On June 4, 2021, the European Commission adopted new standard contractual clauses under the GDPR for data transfers from entities that are subject to the GDPR to transfer personal data outside of the EEA. The new standard contractual clauses impose additional obligations, including the obligation to conduct a transfer impact assessment and, depending on a party's role in the transfer, to implement additional security measures and to update internal privacy practices. If we elect to rely on the standard contractual clauses for data transfers, we may be required to incur significant time and resources to update our contractual arrangements and to comply with new obligations. Additionally, on September 8, 2020, the Swiss Data Protection Authority (the Federal Data Protection and Information Commissioner) concluded that the Swiss-U.S. Privacy Shield does not provide an adequate level of protection for personal data transfer from Switzerland to the U.S. pursuant to the Swiss Federal Act on Data Protection. As

supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of €20.0 million or 4% of total global annual turnover. Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and the EU, we will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million / £17 million or 4% of global turnover. Following December 31, 2020, and the expiry of the post-Brexit transitional arrangements between the United Kingdom and EU, although it is likely that the data protection obligations of the GDPR will continue to apply to UK-related processing of personal data in substantially unvaried form and fashion, for at least the short term thereafter, the relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear. For example, it is not yet clear whether the United Kingdom will be the subject of a so-called adequacy decision of the European Commission, and it is therefore unclear how data transfers between EU/EEA Member States and the United Kingdom will be treated. Any changes relating to the UK and EU position regarding aspects of data protection law may lead to additional compliance costs and could increase our overall risk. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, an inability to process personal data or to operate in certain jurisdictions, or potential civil claims including class action type litigation.

Moreover, we use third-party service providers and subprocessors to help us operate our business and engage in processing on our behalf. If we, our service providers, partners, or other relevant third-parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure or disclosure of sensitive information, or compromise related to the security, confidentiality, integrity of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, or an inability to process data in some jurisdictions. Furthermore, applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security breaches, including affected individuals, customers, and regulators. Such disclosures are costly, and the disclosure or the failure to comply with such requirements, could result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions.

For more information on the potential impact of the GDPR, and associated EEA data protection laws, on our business, see the section titled “Risk Factors—Risks Related to Employee Matters and Our Operations—We are subject to a variety of privacy and data security laws, rules, regulations, policies, industry standards and contractual obligations, and our failure to comply with them could harm our business.”

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in other countries that impose similar obligations.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Facilities

Our principal executive office is located in Watertown, Massachusetts, where we lease a total of 13,711 square feet of office and laboratory space that we use for our administrative, research and development and other activities under a lease that currently expires in April 2028, with an option to extend the term for an additional five years at then-market rental rates. Additionally, we also lease laboratory and office space in Lund, Sweden, which will expire in September 2023, with an option to extend the term for an additional three years. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Employees and Human Capital Resources

As of October 31, 2022, we had 39 full-time employees and three part-time employees. Of our 42 full- and part-time employees, approximately 24 have Ph.D. or M.D. degrees and 34 are engaged in research and development activities. 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 employees. We believe our success depends on our ability to attract, retain, develop and motivate diverse highly skilled personnel. In particular, we depend upon the personal efforts and abilities of the principal members of our senior management to partner effectively as a team, and to provide strategic direction, develop our business, manage our operations and maintain a cohesive and stable work environment. We also rely on qualified managers and skilled employees, such as scientists, engineers and laboratory technicians, with technical expertise in operations, scientific knowledge, engineering skills and quality management experience in order to operate our business successfully.

Our compensation program is designed to retain, motivate and, as needed, attract highly qualified employees. Accordingly, we use a mix of competitive base salary, cash-based annual incentive compensation, performance-based equity compensation awards and other employee benefits.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table provides information regarding our current executive officers and directors, including their ages as of October 31, 2022:

Name	Age	Position(s)
Executive Officers		
Peter Blume-Jensen, M.D., Ph.D.	60	Chief Executive Officer, President and Chairman of the Board
Rasmus Holm-Jorgensen	51	Chief Financial Officer
Erick Gamelin, M.D., Ph.D.	65	Chief Medical Officer
Kristina Masson, Ph.D.	42	Executive Vice President, Business Operations, Director
Eric Devroe, Ph.D.	44	Chief Operating Officer
Non-Employee Directors		
Derek DiRocco, Ph.D.(1)(2)(3)	42	Director
Sharon Shacham, Ph.D., M.B.A.(1)(2)(3)	52	Director
Michael Tomsicek, M.B.A.(1)(2)	56	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Peter Blume-Jensen, M.D., Ph.D., is our main founder and has served as our Chief Executive Officer, acting Chief Scientific Officer, President, and as a member of our board of directors since March 2018, including as chairman of our board of directors since October 2020. Dr. Blume-Jensen previously served as Chief Scientific Officer at XTuit Pharmaceuticals, Inc., a biopharmaceutical company, from 2014 to March 2018 and before that as Chief Scientific Officer at Metamark Genetics, Inc., a biopharmaceutical company, from 2010 to 2014. Prior to that he held several leadership positions in various pharmaceutical companies, including most recently as Vice President, External Scientific Affairs and Global Therapeutic Area Advisor for Oncology at Daiichi Sankyo from 2008 to 2010. He was Department Head, Senior Director, Molecular Oncology at Merck & Co., Inc. from 2005 to 2008 and before that Department Head, Director of Molecular Oncology at EMD Serono, a biopharmaceutical division of Merck KGaA, from 2001 to 2005. He received an M.D. from Copenhagen University Medical School, Denmark, a Ph.D. from The Ludwig Institute for Cancer Research, Uppsala University, Uppsala, Sweden, and conducted his Post-Doctoral Fellowship under Tony Hunter at the Salk Institute. Our board of directors believes that Dr. Blume-Jensen is qualified to serve as a director based on his knowledge of our business as our main founder and chief executive officer, inventor of the founding AP3 platform and his extensive experience in oncology research and development and oncogenic kinase signaling.

Rasmus Holm-Jorgensen has served as our Chief Financial Officer since April 2022. Previously, he served as Senior Vice President, Chief Strategy & Portfolio Officer at Kiniksa Pharmaceuticals, Inc., a biopharmaceutical company, from 2015 to April 2022. Prior to that, Mr. Holm-Jorgensen served as Group Vice President and General Manager at Synageva BioPharma Corp. from 2011 to 2015. Mr. Holm-Jorgensen received an M.S. in economics from the University of Copenhagen.

Erick Gamelin, M.D., Ph.D., has served as our Chief Medical Officer since March 2021. Previously, he served as Chief Medical Officer at Step Pharma, a biotechnology company, from November 2019 to January 2021, Vice President, Oncology at Dynavax Technologies Corporation, a biopharmaceutical company, from March 2018 to October 2019, Vice President at MacroGenics, Inc., a biopharmaceutical company, from August 2017 to March 2018,

and in various leadership positions in the Oncology Vaccine department at Pfizer Inc., a pharmaceutical company, from 2015 to July 2017. Dr. Gamelin is a medical oncologist, former professor of Medical Oncology and CEO of a University Cancer Center, ICO, and a Knight of the French National Order of Merit, appointed by the French Minister of Health. He has co-authored more than 135 international scientific articles in peer-reviewed journals and has founded and led an academic research team: "Genomics and mechanisms of cancer resistance." Dr. Gamelin received a Ph.D. in molecular pharmacology from Bordeaux University and conducted his Post-Doctoral studies in the Molecular Therapeutics Section, Medical Branch, at the National Institutes of Health.

Kristina Masson, Ph.D., is our co-founder and has served as our President, CEO and Site Head of our subsidiary Acrivon AB and as a member of our board of directors since March 2018. Dr. Masson has also served as our Executive Vice President, Business Operations since August 2022 and previously served as our Senior Vice President, Operations from March 2018 to August 2022. In November 2016, Dr. Masson founded OncoSignature AB, a biotechnology company, which she led until its acquisition by Acrivon AB in March 2018. Dr. Masson received an MSc and a Ph.D. from Lund University and conducted her Post-Doctoral Fellowship at the Broad Institute of MIT and Harvard. Our board of directors believes that Dr. Masson is qualified to serve as a director based on her knowledge of our business as a co-founder of the company and OncoSignature AB and her extensive experience in oncology research and development.

Eric Devroe, Ph.D., has served as our Chief Operating Officer since August 2022 and previously served as our Senior Vice President, Business Operations from October 2020 to August 2022. Dr. Devroe has also served as our Corporate Secretary since January 2021. Previously, Dr. Devroe served as Founder & Chief Executive Officer of Xione Therapeutics, Inc., an oncology company, from August 2019 to September 2021, Strategic Advisor, Therapeutics Discovery at the MDACC from May 2018 to October 2019, and Founder & Chief Executive Officer of Opsonix, Inc., an infectious diseases company, from 2015 to May 2018. Dr. Devroe received a B.S. in microbiology from the University of Texas at Austin and a Ph.D. in biological chemistry and molecular pharmacology from Harvard University.

Non-Employee Directors

Derek DiRocco, Ph.D., has served on our board of directors since November 2021. Dr. DiRocco has been a partner at RA Capital Management, LLC, an investment manager, since December 2020 and previously served as principal from December 2017 to December 2020, an analyst from June 2015 to December 2017 and an associate from July 2013 to June 2015. Dr. DiRocco has served on the board of directors of 89bio, Inc. since April 2018, iTeos Therapeutics, Inc. since March 2020, Connect Biopharma Holdings Limited since August 2020, and Werewolf Therapeutics, Inc. since December 2020. He previously served on the board of directors of Achilles Therapeutics plc from September 2019 to May 2022. Dr. DiRocco holds a B.A. in biology from College of the Holy Cross and a Ph.D. in pharmacology from the University of Washington, and conducted his postdoctoral research at Brigham and Women's Hospital/Harvard Medical School. Our board of directors believes that Dr. DiRocco is qualified to serve as a director because of his experience as an investor in biotechnology companies and experience as a director of multiple private and public companies.

Sharon Shacham, Ph.D., M.B.A., has served on our board of directors since October 2020. Dr. Shacham co-founded E44 Ventures in June 2022 and serves as Managing Director. Dr. Shacham founded Karyopharm Therapeutics Inc. in 2008, where she served as Chief Scientific Officer from October 2010 to May 2022, President from October 2013 to May 2021, President of Research and Development from December 2012 to May 2021, Head of Research and Development from October 2010 to December 2012, and President and Chief Executive Officer from October 2010 to January 2011. Dr. Shacham currently serves on Karyopharm's Scientific Advisory Board. Dr. Shacham led the scientific and clinical work that led to the discovery, development and regulatory approval of selinexor (Xpovio). Xpovio is a first-in-class, oral exportin 1 (XPO1) inhibitor and is approved in the United States in multiple oncology indications. Prior to joining Karyopharm, Dr. Shacham served as Senior Vice President of Drug Development at Epix Pharmaceuticals, Inc., and Director, Algorithm and Software Development at Predix Pharmaceuticals Inc., which merged into Epix Pharmaceuticals in 2006, where

she led the company's efforts in GPCR modeling, computational chemistry, lead optimization and development of clinical trials. Dr. Shacham holds a B.S. in chemistry, a Ph.D. in biophysical chemistry, and an M.B.A. from Tel Aviv University. Our board of directors believes that Dr. Shacham is qualified to serve as a director because of her extensive experience as an executive officer in the biopharmaceutical industry.

Michael Tomsicek*, *M.B.A. has served on our board of directors since October 2022. Mr. Tomsicek has served as a member of the board of directors of Milestone Pharmaceuticals USA, Inc., a Nasdaq-listed biopharmaceutical company, since April 2019. Mr. Tomsicek served as the Chief Financial Officer of CRISPR Therapeutics AG, a Nasdaq-listed gene editing company, from November 2017 through October 2021. Prior to that, Mr. Tomsicek served as Chief Financial Officer of Abiomed, Inc., a Nasdaq-listed medical device company, from July 2015 to August 2017. Before that, he was Chief Financial Officer at Cubist Pharmaceuticals, Inc., or Cubist, a Nasdaq-listed biopharmaceutical company. He was at Cubist from August 2010 to January 2015, through the company's sale to Merck, and held a series of roles of increasing responsibility leading finance, investor relations and strategic sourcing. Prior to Cubist, Mr. Tomsicek spent nearly eight years at General Electric Healthcare, ultimately as Chief Financial Officer of the global ultrasound business. Mr. Tomsicek holds an M.B.A. and a B.S. in Engineering, both from the University of Wisconsin. Our board of directors believes that Mr. Tomsicek is qualified to serve as a director because of his management and industry experience, including his public company management experience.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of five members. Our directors were elected to, and currently serve on, the board pursuant to a voting agreement among us and substantially all of our stockholders and voting rights granted by our current amended and restated certificate of incorporation. The voting agreement will terminate upon the closing of this offering, after which there will be no further contractual obligations regarding the election of our directors.

In accordance with our amended and restated certificate of incorporation that will be in effect upon the closing of this offering, our board of directors will be divided into three classes, each of which will consist, as nearly as possible, of one-third of the total number of directors constituting our entire board and which will serve staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- Class I, which will consist of Mr. Tomsicek, and his term will expire at our first annual meeting of stockholders to be held after the closing of this offering;
- Class II, which will consist of Dr. Masson and Dr. Shacham, and their terms will expire at our second annual meeting of stockholders to be held after the closing of this offering; and
- Class III, which will consist of Dr. Blume-Jensen and Dr. DiRocco, and their terms will expire at our third annual meeting of stockholders to be held after the closing of this offering.

Our amended and restated bylaws, which will become effective upon the closing of this offering, will provide that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control.

Director Independence

Applicable Nasdaq rules, or the Nasdaq Listing Rules, require a majority of a listed company's board of directors to be composed of independent directors within one year 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 corporate governance committees be independent and that audit committee members also satisfy

independence criteria set forth in Rule 10A-3 under the Exchange Act of 1934, as amended, or the Exchange Act. The Nasdaq independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees, that neither the director nor any of his family members has engaged in various types of business dealings with us and that the director is not associated with the holders of more than 5% of our common stock. In addition, under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed 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.

Our board of directors has determined that all of our directors other than Peter Blume-Jensen, M.D., Ph.D., and Kristina Masson, Ph.D., representing three of our five directors, are "independent directors" as defined under applicable Nasdaq rules. In making such determination, our board of directors considered the current and prior relationships that each such director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each director and the transactions described in the section titled "Certain Relationships and Related Party Transactions."

There are no family relationships among any of our directors or executive officers except that Dr. Blume-Jensen and Dr. Masson are married.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure. Following the completion of this offering, we intend for our audit committee to have the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee will also monitor compliance with legal and regulatory requirements.

Board Committees

Our board of directors has established an audit committee, compensation committee and a nominating and corporate governance committee, each of which operate pursuant to a committee charter. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below.

Audit Committee

Upon the completion of this offering, our audit committee will consist of Mr. Tomsicek, Dr. Shacham and Dr. DiRocco, with Mr. Tomsicek serving as chair of the audit committee. Our board of directors has determined that each of these individuals meets the independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934, or the Exchange Act, and the applicable listing standards of Nasdaq. Each member of our audit committee can read and understand fundamental financial statements in accordance with Nasdaq audit committee requirements. Our board of directors has also determined that Mr. Tomsicek qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In arriving at these determinations, the board has examined each audit committee member's scope of experience and the nature of their prior and/or current employment.

The functions of this committee include, among other things:

- helping our board of directors oversee our corporate accounting and financial reporting processes;

- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually that describes our internal quality control procedures, any material issues with such procedures and any steps taken to deal with such issues when required by applicable law; and
- approving or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

We believe that the composition and functioning of our audit committee will comply with all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

Upon the completion of this offering, our compensation committee will consist of Mr. Tomsicek, Dr. Shacham and Dr. DiRocco, with Mr. Tomsicek serving as chair of the compensation committee. Each of these individuals is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act and is an "outside director," as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code. Our board of directors has determined that each of these individuals is ''independent'' as defined under the applicable listing standards of Nasdaq, including the standards specific to members of a compensation committee. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- making recommendations to the full board of directors regarding the compensation and other terms of employment of our executive officers;
- reviewing and making recommendations to the full board of directors regarding performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation to the extent required by Section 14A of the Exchange Act and, if applicable, determining our recommendations regarding the frequency of advisory votes on executive compensation;

- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and making recommendations to the full board of directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and evaluating on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee will comply with all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Corporate Governance Committee

Upon the completion of this offering, our nominating and corporate governance committee will consist of Dr. DiRocco and Dr. Shacham, with Dr. DiRocco serving as chair of the nominating and corporate governance committee. Our board of directors has determined that each of these individuals is ''independent'' as defined under the applicable listing standards of Nasdaq and SEC rules and regulations. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles and recommending to our board of directors any changes to such policies and principles;
- reviewing and making recommendations to the board of directors with respect to management succession planning;
- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and evaluating on an annual basis the performance of the nominating and corporate governance committee and the nominating and corporate governance committee charter.

We believe that the composition and functioning of our nominating and corporate governance committee will comply with all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee Interlocks and Insider Participation

None of our directors who serve as a member of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics or the Code of Conduct, effective upon the closing of this offering, applicable to all of our employees, executive officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. Following the closing of this offering, the full text of the Code of Conduct will be available on our website at *www.acrivon.com*. We intend to post on our website all disclosures that are required by law or the listing standards of the Nasdaq Stock Market concerning any amendments to, or waivers from, any provision of the Code of Conduct. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

Non-Employee Director Compensation

We did not pay compensation to any of our non-employee directors during the year ended December 31, 2021. Dr. Blume-Jensen, our Chief Executive Officer and President, and Dr. Masson, our Executive Vice President, Business Operations, are also members of our board of directors, but did not receive any additional compensation for their service as a director during this period.

Non-Employee Director Compensation Policy

Our board of directors adopted a non-employee director compensation policy in October 2022 that will become effective upon the pricing of this offering and will be applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the compensation described below for service on our board of directors:

Cash compensation. Under this policy, we will pay each of our non-employee directors cash retainers for service on our board of directors and committees of our board of directors as follows:

	Annual Cash Retainer ($)
Annual retainer	40,000
Additional retainer for lead independent director	20,000
Additional retainer for audit committee chair	15,000
Additional retainer for audit committee non-chair member	7,500
Additional retainer for compensation committee chair	15,000
Additional retainer for compensation committee non-chair member	7,500
Additional retainer for nominating and corporate governance committee chair	10,000
Additional retainer for nominating and corporate governance committee non-chair member	5,000

We will also reimburse each non-employee director for any ordinary and reasonable out-of-pocket expenses actually incurred by such director in connection with in-person attendance at and participation in meetings of our board of directors and committees of our board of directors.

Equity compensation. In addition to cash compensation, each non-employee director will be eligible to receive options under our 2022 Plan. All options granted under the policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the fair market value of the underlying common stock on the date of grant, and a term of ten years from the date of grant, subject to earlier termination in connection with a

termination of service. Vesting schedules for equity awards will be subject to the non-employee director's continuous service on each applicable vesting date, provided that each option will vest in full upon a change in control of the company, as defined in the 2022 Plan.

Initial award. Each new non-employee director elected or appointed to our board of directors after the effective date of the policy will automatically be granted an initial, one-time stock option award having an aggregate grant date fair value of $315,000, provided that the number of shares underlying such option shall not exceed 32,500 shares. The initial option grant will vest in substantially equal monthly installments over a three-year period such that the option is fully vested on the third anniversary of the grant date.

Annual awards. On the date of each annual meeting of stockholders of our company after the effective date of the policy, commencing with the 2024 annual meeting of stockholders, each non-employee director that continues to serve on our board of directors will automatically be granted a stock option award having an aggregate grant date fair value of $210,000, provided that the number of shares underlying such option shall not exceed 20,275 shares. The grant date fair value of the annual option grant shall be prorated for non-employee directors who have served on our board of directors for less than one year as of such annual meeting. The annual option grant shall vest in substantially equal monthly installments over a one-year period such that the option is fully vested on the first anniversary of the grant date, provided that such option will in any case become fully vested on the date immediately preceding the date of our next annual stockholder meeting.

Non-employee director compensation limit. The cash and equity compensation that each non-employee director is eligible to receive under the policy will be subject to the director compensation limits set forth in the 2022 Plan.

Director IPO Option Grants

On the date of the pricing of this offering, each of our non-employee directors will receive an option to purchase a number of shares of common stock with an aggregate grant date fair value of $315,000 (which, based on an assumed initial public offering price of $17.00 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, will be 25,905 shares of common stock), which will have an exercise price equal to the initial public offering price, and will vest in 36 equal monthly installments such that each such option is fully vested on the third anniversary of the grant date.

EXECUTIVE COMPENSATION

Our named executive officers for the fiscal year ended December 31, 2021, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- Peter Blume-Jensen, M.D., Ph.D., who currently serves as our Chief Executive Officer and President and as a member of our board of directors;
- Erick Gamelin, M.D., Ph.D., who currently serves as our Chief Medical Officer; and
- Eric Devroe, Ph.D., who currently serves as our Chief Operating Officer.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by and paid to our named executive officers with respect to the year ended December 31, 2021.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-equity Incentive Plan Compensation ($)	Total ($)
Peter Blume-Jensen, M.D., Ph.D. *Chief Executive Officer, President and Director*	2021	430,000	111,771	215,000	756,771
Erick Gamelin, M.D., Ph.D. *Chief Medical Officer*	2021	360,000	57,355	120,723	538,078
Eric Devroe, Ph.D. *Chief Operating Officer*	2021	300,000	87,939	75,000	462,939

(1) Option awards in this column are reported at the aggregate grant date fair value in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 11 to our audited consolidated financial statements included in this registration statement. This amount does not reflect the actual economic value that may be realized by the named executive officer.

Narrative to the Summary Compensation Table

Annual Base Salary

Our named executive officers receive a base salary to compensate them for services rendered to us. 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. Dr. Blume-Jensen's, Dr. Gamelin's and Dr. Devroe's respective annual base salaries were $430,000, $360,000 and $300,000 for the year ended December 31, 2021.

Non-Equity Incentive Plan Compensation

Our named executive officers are eligible to receive annual incentive compensation based on the satisfaction of individual and corporate performance objectives established by the Board. Each named executive officer has a target annual incentive opportunity, calculated as a percentage of annual base salary. For 2021, the target annual incentive opportunities as a percentage of base salary for our named executive officers were 50% for Dr. Blume-Jensen, 40% for Dr. Gamelin and 25% for Dr. Devroe. The amounts of any annual incentives earned are determined after the end of the year, based on the achievement of the designated corporate and individual performance objectives, and may be paid in cash or equity. For 2021, our board of directors determined that the corporate performance goals had been achieved at a 100% level, which resulted in the aggregate payouts for each named executive officer in the amounts reflected in the column of the Summary Compensation Table above entitled "Non-Equity Incentive Plan Compensation."

Equity-Based Incentive Awards

We believe that equity awards 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. To date, we have only used stock option grants for this purpose because we believe they are an effective means by which to align the long-term interests of our executive officers with those of our stockholders. The use of stock options also can provide tax and other advantages to our executive officers relative to other forms of equity compensation. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees.

We award stock options broadly to our employees, including to our non-executive employees. Grants to our executives and other employees are made at the discretion of our board of directors and are not made at any specific time period during a year.

Prior to this offering, all of the stock options we have granted were made pursuant to our 2019 Plan. Following this offering, we will grant equity incentive awards under the terms of our 2022 Plan. The terms of our equity plans are described under the section titled "Executive Compensation—Equity Incentive Plans" below.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth certain information about outstanding equity awards granted to our named executive officers that were outstanding as of December 31, 2021.

			Option Awards[1]			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Peter Blume-Jensen, M.D., Ph.D. *Chief Executive Officer, President and Director*	1/14/2021	10/5/2020	89,888	76,059[2]	$ 1.04	1/13/2031
Erick Gamelin, M.D., Ph.D. *Chief Medical Officer*	3/25/2021	3/1/2021	—	81,103[3]	$ 1.04	3/24/2031
Eric Devroe, Ph.D. *Chief Operating Officer*	1/14/2021	10/5/2020	31,528	94,586[4]	$ 1.04	1/13/2031

(1) All of the option awards were granted under the 2019 Plan. All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant.

(2) The unvested shares underlying this option vest in 36 equal monthly installments until October 31, 2023, subject to the officer's continued service through each applicable vesting date.

(3) The unvested shares underlying this option vest in 16 equal quarterly installments until March 1, 2025, subject to the officer's continued service through each applicable vesting date.

(4) The unvested shares underlying this option vest in 16 equal monthly installments until October 5, 2024, subject to the officer's continued service through each applicable vesting date.

In October 2022, our board of directors approved the grant of options to Dr. Blume-Jensen, Dr. Gamelin and Dr. Devroe, effective upon the pricing of this offering, to purchase a number of shares that will be equal to 0.675%, 0.225% and 0.375%, respectively, of our total outstanding shares as of such date, on a fully diluted basis after giving effect to this offering. These options will have an exercise price equal to the initial public offering price. The shares underlying these options will vest as to 25% on the one-year anniversary of the grant date, with the remainder vesting in 36 equal monthly installments thereafter, subject to the named executive officer's continued service through each applicable vesting date. In addition, our board of directors approved the grant of

restricted stock units to Dr. Blume-Jensen, Dr. Gamelin and Dr. Devroe, effective upon the pricing of this offering, for a number of shares equal to 0.225%, 0.075% and 0.125%, respectively, of our total outstanding shares as of such date, on a fully diluted basis after giving effect to this offering. The shares underlying these restricted stock units will vest as to 25% on the one-year anniversary of the grant date, with the remainder vesting in 12 equal quarterly installments thereafter, subject to the named executive officer's continued service through each applicable vesting date. Our board of directors also approved an additional grant of restricted stock units to Dr. Blume-Jensen, effective upon the pricing of this offering, for a number of shares equal to 3.5% plus an additional 1.885% meant to cover estimated tax liability at the time of settlement, for a total of 5.385% of our total outstanding shares as of the pricing of this offering, on a fully diluted basis after giving effect to this offering. One-third of the shares underlying this restricted stock unit grant will vest on the one-year anniversary of the grant date, with the remainder vesting in eight equal quarterly installments thereafter, subject to the named executive officer's continued service through each applicable vesting date.

Notwithstanding the foregoing, in the event that, in connection with or during the period ending 12 months following the consummation of a change in control, we terminate the named executive officer for any reason other than for cause, any portion of the options or restricted stock units described above, as applicable, that is outstanding and unvested as of the date shall immediately accelerate and vest in full as of the date of such termination (or, if later, the date of such change in control).

See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates—Stock-Based Compensation Expense" for additional information on the related stock-based compensation expense associated with the awards granted to our executives in connection with this offering.

Employment Agreements with Named Executive Officers and Potential Payments and Benefits Upon Termination or Change in Control

We have entered into employment agreements with our named executive officers, and in connection with this offering, we expect to enter into amended and restated employment agreements with our named executive officers to supersede their prior employment agreements. The key terms of the current agreements are described below. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment or a change in control under the arrangements with our named executive officers, please see the section titled "Potential Payments Upon Termination of Employment or Change in Control in the Prior Employment Agreements" below.

Employment Agreements with our Named Executive Officers

Peter Blume-Jensen, M.D., Ph.D.

Dr. Blume-Jensen's employment agreement originally included a base salary of $430,000 and an annual target bonus of 50% of his base salary. In March 2022, our board of directors approved an increase to Dr. Blume-Jensen's base salary to $520,000, effective retroactively to January 1, 2022. In October 2022, our board of directors approved an increase to Dr. Blume-Jensen's base salary to $610,000 and an increase of his annual target bonus to 55% of his base salary, each effective upon the effectiveness of the Registration Statement of which this prospectus is a part. The annual bonus will be determined by the board of directors based on achievement of targets and milestones for our performance and Dr. Blume-Jensen's performance for the applicable calendar year. The employment agreement provides for standard benefits, such as vacation, reimbursement of business expenses, and participation in our employee benefit plans and programs. Upon a termination without cause, we have agreed to provide Dr. Blume-Jensen a minimum of sixty days' notice of such termination.

Erick Gamelin, M.D., Ph.D.

Dr. Gamelin's employment agreement originally included a base salary of $360,000 and an annual target bonus of 40% of his base salary. In March 2022, our board of directors approved an increase to Dr. Gamelin's base salary to $410,000, effective retroactively to January 1, 2022. In October 2022, our board of directors approved an increase to Dr. Gamelin's base salary to $465,000, effective upon the effectiveness of the Registration Statement of which this prospectus is a part. The annual bonus will be determined by the board of directors based on our and Dr. Gamelin's performance against corporate goals for the applicable calendar year. The employment agreement provides for standard benefits, such as vacation and participation in our employee benefit plans and programs.

Eric Devroe, Ph.D.

Dr. Devroe's employment agreement originally included a base salary of $300,000 and an annual target bonus of 25% of his base salary. In March 2022, our board of directors approved an increase to Dr. Devroe's base salary to $370,000, effective retroactively to January 1, 2022. In October 2022, our board of directors approved an increase to Dr. Devroe's base salary to $475,000 and an increase of his annual target bonus to 40% of his base salary, each effective upon the effectiveness of the Registration Statement of which this prospectus is a part. The annual bonus will be determined by the board of directors based on our and Dr. Devroe's performance against corporate goals for the applicable calendar year. The employment agreement provides for standard benefits, such as vacation and participation in our employee benefit plans and programs.

Potential Payments Upon Termination of Employment or Change in Control in the Prior Employment Agreements

Dr. Blume-Jensen

In the event that Dr. Blume-Jensen's employment terminates, other than during the three months prior to, or within a twelve month period following, the consummation of a change of control, by us without "cause" or by Dr. Blume-Jensen for "good reason" (as defined in the employment agreement), and subject to Dr. Blume-Jensen's execution of a separation agreement with a general release of claims in our favor, and standard terms relating to non-disparagement, confidentiality, cooperation and the like (the "CEO Severance Conditions"), Dr. Blume-Jensen will receive (i) cash severance in the form of continuation of his base salary for a period of twelve months; (ii) a pro-rata portion of his target bonus for the year in which termination occurs; (iii) continuation of health benefits for a period of up to twelve months; and (iv) continued vesting of all outstanding time-based equity awards that would otherwise have vested had he remained employment for an additional twelve months after the separation date.

In the event that Dr. Blume-Jensen's employment terminates without cause or upon Dr. Blume-Jensen's resignation for good reason within the Change of Control Period, and subject to Dr. Blume-Jensen's satisfaction of the CEO Severance Conditions, Dr. Blume-Jensen will receive (i) cash severance in the form of a lump sum payment equal to eighteen months of his base salary; (ii) 100% of his target bonus; (iii) continuation of health benefits for a period of up to eighteen months; and (iv) full acceleration of all outstanding time-based equity awards held by Dr. Blume-Jensen.

Dr. Gamelin

In the event that Dr. Gamelin's employment terminates, other than during the period ending twelve months after a change of control, by us without "cause" or by Dr. Gamelin for "good reason" (as defined in the employment agreement), and subject to Dr. Gamelin's execution of a general release of claims, Dr. Gamelin will receive cash severance in the form of continuation of his base salary for a period of six months. In the event that Dr. Gamelin's employment terminates without cause or upon Dr. Gamelin's resignation for good reason within

the Change of Control Period, and subject to Dr. Gamelin's execution of a general release of claims in our favor, Dr. Gamelin will receive (i) cash severance in the form of a lump sum payment equal to six months of his base salary and (ii) full acceleration of all unvested shares and unexercised options held by Dr. Gamelin as of the date of termination.

Dr. Devroe

In the event that Dr. Devroe's employment terminates, other than during the period ending twelve months after a change of control, by us without "cause" or by Dr. Devroe for "good reason" (as defined in the employment agreement), and subject to Dr. Devroe's execution of a separation agreement with a general release of claims in our favor, Dr. Devroe will receive cash severance in the form of continuation of his base salary for a period of six months. In the event that Dr. Devroe's employment terminates, within the Change of Control Period, by us without "cause" or by Dr. Devroe for "good reason" (as defined in the employment agreement), and subject to Dr. Devroe's execution of a separation agreement with a general release of claims in our favor, Dr. Devroe will receive (i) cash severance in the form of a lump sum payment equal to six months of his base salary in effect at the time of his separation and (ii) full acceleration of all unvested shares and unexercised options held by Dr. Devroe as of the date of termination.

Retirement Benefits and Other Compensation

Our named executive officers are eligible to participate in our employee benefits, including health insurance and group life insurance benefits, on the same basis as our other employees. In addition, we maintain a 401(k) profit sharing plan pursuant to Section 401(k) of the Code covering all eligible employees. We make profit sharing contributions to qualifying participants pursuant to a discretionary formula. We generally do not provide other perquisites or personal benefits except in limited circumstances, and we did not provide any such perquisites or personal benefits to our named executive officers in 2021.

Equity Incentive Plans

2022 Equity Incentive Plan

Our board of directors adopted the 2022 Plan in October 2022 and our stockholders approved the 2022 Plan in October 2022. The 2022 Plan will become effective on the date of the underwriting agreement related to this offering. Our 2022 Plan will come into existence upon its adoption by our board of directors, but no grants will be made under our 2022 Plan prior to its effectiveness. Once our 2022 Plan becomes effective, no further grants will be made under our 2019 Plan.

Types of Awards. Our 2022 Plan provides for the grant of incentive stock options, or ISOs, nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based awards and other awards, or collectively, awards. ISOs may be granted only to our employees, including our officers, and the employees of our affiliates. All other awards may be granted to our employees, including our officers, our non-employee directors and consultants and the employees and consultants of our affiliates.

Authorized Shares. The maximum number of shares of common stock that may be issued under our 2022 Plan is 5,606,723 shares, which is the sum of: (i) 2,555,271 new shares, plus (ii) the number of shares that remain available for issuance under the 2019 Plan at the time our 2022 Plan becomes effective and (iii) up to 2,148,679 shares of our common stock subject to awards granted under our 2019 Plan that, after the effective date of our 2022 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us. The number of shares of common stock reserved for issuance under our 2022 Plan will automatically increase on January 1 of each year, beginning on January 1, 2023, and continuing through and including January 1, 2032, by 5% of the aggregate number of shares of common stock of all classes issued and outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors prior to the applicable January 1. The maximum number of shares that may be issued upon the exercise of ISOs under our 2022 Plan is 16,820,169 shares.

In October 2022, pursuant to the 2022 Plan, effective upon the pricing of this offering, our board of directors approved the grants of options to purchase (i) a number of shares that will equal an aggregate of 2.96% of our total outstanding shares as of such date, on a fully diluted basis after giving effect to this offering, to our existing employees and consultants (inclusive of the grants to our named executive officers described above), (ii) a number of shares with an aggregate grant date fair value of $945,000 to our non-employee directors as described above, and (iii) an aggregate of 200,883 shares to our new employees. All such options will have an exercise price equal to the initial public offering price. In addition, pursuant to the 2022 Plan, effective upon the pricing of this offering, our board of directors approved the grants of restricted stock units (i) for an aggregate of 6.37% of our total outstanding shares as of such date, on a fully diluted basis after giving effect to this offering, to our existing employees and consultants (inclusive of the grants to our named executive officers described above) and (ii) for 66,962 shares to our new employees.

Shares issued under our 2022 Plan will be authorized but unissued or reacquired shares of common stock. Shares subject to awards granted under our 2022 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2022 Plan. Additionally, shares issued pursuant to awards under our 2022 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of an award or to satisfy the tax withholding obligations to an award, will become available for future grant under our 2022 Plan.

The maximum number of shares of common stock subject to stock awards granted under the 2022 Plan or otherwise during any calendar year beginning in 2023 to any non-employee director, taken together with any cash fees paid by us to such non-employee director during such calendar year for service on the board of directors, will not exceed $750,000 in total value (calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes).

Plan Administration. Our board of directors, or a duly authorized committee of our board, may administer our 2022 Plan. Our board of directors has delegated concurrent authority to administer our 2022 Plan to the compensation committee under the terms of the compensation committee's charter. We sometimes refer to the board of directors, or the applicable committee with the power to administer our equity incentive plans, as the administrator. The administrator may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified awards, and (2) determine the number of shares subject to such awards.

The administrator has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of awards, if any, the number of shares subject to each award, the fair market value of a share of common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2022 Plan.

In addition, subject to the terms of the 2022 Plan, the administrator also has the power to modify outstanding awards under our 2022 Plan, including the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the administrator. The administrator determines the exercise price for a stock option, within the terms and conditions of the 2022 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2022 Plan vest at the rate specified in the stock option agreement as specified in the stock option agreement by the administrator.

The administrator determines the term of stock options granted under the 2022 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's

service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO and (5) other legal consideration approved by the administrator.

Options may not be transferred to third-party financial institutions for value. Unless the administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will be treated as NSOs. No ISOs may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations, unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the administrator. Restricted stock awards may be granted in consideration for cash, check, bank draft or money order, services rendered to us or our affiliates or any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the administrator. A restricted stock award may be transferred only upon such terms and conditions as set by the administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested may be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation right grant agreements adopted by the administrator. The administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is

exercised. A stock appreciation right granted under the 2022 Plan vests at the rate specified in the stock appreciation right agreement as determined by the administrator.

The administrator determines the term of stock appreciation rights granted under the 2022 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provide otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. Our 2022 Plan permits the grant of performance-based stock and cash awards. The compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The compensation committee may establish performance goals on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, the compensation committee will appropriately make adjustments in the method of calculating the attainment of the performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Awards. The administrator may grant other awards based in whole or in part by reference to common stock. The administrator will set the number of shares under the award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2022 Plan; (2) the class and maximum number of shares by which the share reserve may increase automatically each year; (3) the class and maximum number of shares that may be issued upon the exercise of ISOs and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding awards.

Corporate Transactions. The following applies to stock awards under the 2022 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant. Under the 2022 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

In the event of a corporate transaction, any stock awards outstanding under the 2022 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction. In addition, the plan administrator may also provide, in its sole discretion, that the holder of a stock award that will terminate upon the occurrence of a corporate transaction if not previously exercised will receive a payment, if any, equal to the excess of the value of the property the participant would have received upon exercise of the stock award over the exercise price otherwise payable in connection with the stock award.

Stock options granted under the 2022 Plan become vested and exercisable in full in the event the holder's service is terminated without cause in connection with or within 12 months following a change in control, unless otherwise provided in the applicable option agreement. Other stock awards may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in an applicable award agreement or other written agreement, but in the absence of such provision, no such acceleration will occur.

Transferability. A participant may not transfer awards under our 2022 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2022 Plan.

Plan Amendment or Termination. Our board has the authority to amend, suspend or terminate our 2022 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board adopted our 2022 Plan. No awards may be granted under our 2022 Plan while it is suspended or after it is terminated.

2019 Stock Incentive Plan

Our board of directors adopted, and our stockholders approved, our 2019 Plan in June 2019. No further stock awards will be granted under our 2019 Plan on or after the effectiveness of our 2022 Plan; however, awards outstanding under our 2019 Plan will continue to be governed by their existing terms.

Types of Awards. Our 2019 Plan allows us to grant ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock units and other awards to eligible employees, directors, officers, consultants and advisors of ours and any parent or subsidiary of ours.

Authorized Shares. An aggregate of 3,077,023 shares of our common stock were reserved for issuance under our 2019 Plan. As of June 30, 2022, options to purchase 2,072,851 shares of our common stock remained outstanding under our 2019 Plan. In the event that an outstanding option, restricted stock award or other award for any reason expires or is canceled, the shares allocable to such award shall be added to the number of shares then available for issuance under our 2022 Plan once adopted by our board of directors and approved by our stockholders.

Plan Administration. Our board of directors or a committee of our board administers our 2019 Plan. Subject to the provisions of the 2019 Plan, the administrator has the full authority and discretion to take any actions it deems necessary or advisable for the administration of the 2019 Plan. All decisions, interpretations and other actions of the administrator are final and binding on all participants in the 2019 Plan.

Options. Stock options have been granted under our 2019 Plan. Subject to the provisions of our 2019 Plan, the administrator determines the term of an option, the number of shares subject to an option, and the time period in which an option may be exercised. The term of an option is stated in the applicable award agreement, but the term of an option may not exceed 10 years from the grant date. The administrator determines the exercise price of options, which may not be less than 100% of the fair market value of our common stock on the grant date. To the extent that the aggregate fair market value of the shares with respect to which ISOs are exercisable for the first time by an employee during any calendar year (under all our plans and any parent or subsidiary) exceeds $100,000, such options will be treated as NSOs. The administrator determines how a participant may pay the exercise price of an option, and the permissible methods are generally set forth in the applicable award agreement. If a participant's employment, or relationship with us as a director, consultant or advisor, terminates, that participant may exercise the vested portion of his or her option for the period of time stated in the applicable award agreement. Vested options generally will remain exercisable for 90 days or such longer period of time as set forth in the applicable award agreement if a participant's service to us terminates for a reason other than death, disability or for "cause." If a participant's continuous service terminates due to disability or death, then vested options generally remain exercisable for one year from the date of termination (or such longer period as set forth in the applicable award agreement). In no event will an option remain exercisable beyond its original term. If a participant does not exercise his or her option within the time specified in the award agreement, the option will terminate. Except as described above, the administrator has the discretion to determine the post-termination exercisability periods for an option. In general, stock options granted under the 2019 Plan prior to March 22, 2022 become vested and exercisable in full upon the occurrence of a change in control transaction, provided that the employee remains employed with us at the time of such change in control. Stock options granted under the 2019 Plan beginning on March 22, 2022 become vested and exercisable in full in the event the holder's service is terminated without cause in connection with or within 12 months following a change in control.

Certain Adjustments. In the event of any change that is made in, or other events that occur with respect to, the common stock subject to the 2019 Plan without the receipt of consideration by us through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restricting transaction (but excluding the conversion of any of our convertible securities), the administrator will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the 2019 Plan, (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of ISOs and (iii) the class(es) and number of securities and price per share of stock subject to outstanding awards.

Reorganization Events. The following applies to awards under the 2019 Plan in the event of a reorganization event, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant. Under the 2019 Plan, a reorganization event is generally (1) a merger, consolidation or similar transaction following which we are not the surviving corporation, (2) any transfer or disposition of all of the shares of our common stock, or (3) any liquidation or dissolution.

In the event of a reorganization event, our administrator generally may take one or more of the following actions, contingent upon the closing or completion of such reorganization event: (i) arrange for the surviving corporation or acquiring corporation (or parent company) to assume or continue the award or substitute a similar award, (ii) provide for the termination of all unexercised awards immediately prior to the consummation of the reorganization event, (iii) accelerate the vesting, in whole or in part, of the stock award to a date prior to or upon the effective time of such reorganization event as our administrator determines, (iv) make a payment, in such form as may be determined by our administrator, equal to the excess, if any, of (A) the value of the property the participant would have received upon exercise of the award immediately prior to the effective time of the reorganization event over (B) any exercise price payable, or (v) in connection with a liquidation or dissolution, provide that awards will convert into the right to receive liquidation proceeds (net of any applicable exercise or purchase price).

Transferability of Awards. Unless our administrator provides otherwise, our 2019 Plan generally does not allow for the transfer or assignment of awards, except by will or by the laws of descent and distribution. Shares issued upon exercise or settlement of an award will be subject to such terms and conditions as the administrator may determine, including rights of first refusal and other transfer restrictions.

Amendment; Termination. Our board of directors may amend, suspend or terminate our 2019 Plan at any time, provided that such action does not materially and adversely affect a participant's rights under outstanding awards without such participant's written consent. As noted above, in connection with this offering, our 2019 Plan will be terminated and no further awards will be granted thereunder. All outstanding awards will continue to be governed by their existing terms.

2022 Employee Stock Purchase Plan

Our board of directors adopted our ESPP in October 2022 and our stockholders approved our ESPP in October 2022. The ESPP will become effective on the date of the underwriting agreement related to this offering. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component permits the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the U.S. while complying with applicable foreign laws.

Share Reserve. Following this offering, the ESPP authorizes the issuance of shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The maximum aggregate number of shares of common stock that may be issued under our ESPP is 215,000 shares. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2023 (assuming the ESPP becomes effective in 2022) through January 1, 2032, by the lesser of (1) 1.0% of the total number of shares of our common stock outstanding on the last day of the fiscal year before the date of the automatic increase; provided that before the date of any such increase, our board of directors may determine that such increase will be less than 1.0%. As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors administers the ESPP and may delegate its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to the percentage of earnings or maximum dollar amount specified by our board of directors for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (1) 85% of the fair market value of a share of our common stock on the first date of an offering, or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (1) being customarily employed for more than 20 hours per week, (2) being customarily employed for more than five months per calendar year, or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (1) the class(es) and maximum number of shares reserved under the ESPP, (2) the class(es) and maximum number of shares by which the share reserve may increase automatically each year, (3) the class(es) and number of shares subject to and purchase price applicable to outstanding offerings and purchase rights, and (4) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain significant corporate transactions, including the consummation of (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, or (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately.

ESPP Amendment or Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Limitations on Liability and Indemnification Matters

Upon the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors or officers for monetary damages for breach of fiduciary duty to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;

- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation that will be in effect upon the closing of this offering will provide that we are authorized to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws that will be in effect upon the closing of this offering will provide that we are required to indemnify our directors and executive officers to the fullest permitted by Delaware law, and authorized to indemnify other officers to the same extent. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director or executive officer, and may advance expenses incurred by other officers, in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity to the fullest extent not prohibited by applicable law. Our amended and restated bylaws will also permit us to enter into individual contracts with any of our directors, officers, employees and other agents respecting indemnification and advances, to the fullest extent not prohibited by applicable law.

In connection with this offering, we expect to enter into indemnification agreements with each of our directors and executive officers. With certain exceptions, these agreements will provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers. We maintain directors' and officers' liability insurance and will obtain customary directors' and officers' liability insurance prior to the closing of this offering.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2019 to which we have been a participant in which the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our directors, executive officers or holders of more than 5% of our voting securities, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under "Management—Non-Employee Director Compensation" and "Executive Compensation."

Private Placements of Our Securities

Convertible Promissory Notes

In June and December 2019, we issued and sold convertible promissory notes, or the Convertible Notes, in the aggregate principal amount of $3.0 million. The Convertible Notes accrued interest at a rate of 8% per annum.

The following table sets forth the aggregate principal amount of the Convertible Notes issued to our directors, officers and holders of more than 5% of our capital stock and their affiliates.

Name	Aggregate Principal Amount ($)
Chione Limited[1]	1,000,000

(1) Marcin Czernik, a former member of our board of directors, is a director of Chione Limited. Chione Limited holds more than 5% of our capital stock prior to this offering.

Series A-1 Preferred Stock Financing

In October 2020, we entered into a Series A-1 preferred stock purchase agreement, or the Series A-1 Purchase Agreement, with certain investors, including a beneficial owner of greater than 5% of our capital stock and an affiliate of a member of our board of directors, pursuant to which we issued and sold to such investors an aggregate of 1,315,789 shares of our Series A-1 preferred stock, par value $0.001 per share, or Series A-1 Preferred Stock, at a purchase price of $2.28 per share for aggregate gross proceeds of $3.0 million and issued 3,106,561 shares of our Series A-1 Preferred Stock upon conversion of outstanding convertible promissory notes, including the Convertible Notes, to the holders thereof.

Under the Series A-1 Purchase Agreement, Chione was required to purchase up to $12,000,000 of additional shares of our Series A-1 Preferred Stock upon our achievement of certain milestones, provided that a third-party investor mutually acceptable to us and Chione could purchase all or any portion of such additional shares and the aggregate amount and price per share of such additional shares could be increased upon the mutual agreement of the purchasers of such shares and us.

In January 2021, upon the achievement of certain milestones, we issued and sold to such investors an aggregate of 5,482,456 shares of our Series A-1 Preferred Stock at a purchase price of $2.28 per share for aggregate gross proceeds of $12.5 million.

The table below sets forth the aggregate number of shares of Series A-1 Preferred Stock issued to our related parties in this financing:

Name	Series A-1 Preferred Stock (#)	Aggregate Purchase Price ($)
Chione Limited[1]	8,497,692	18,005,506
New Enterprise Associates 16, LP[2]	1,187,816	2,166,575

(1) Marcin Czernik, a former member of our board of directors, is a director of Chione Limited. Chione Limited holds more than 5% of our capital stock prior to this offering.
(2) New Enterprise Associates 16, LP became a beneficial owner of more than 5% of our capital stock in connection with this transaction.

Reimbursement of Expenses Related to Patent License Agreement with Peter Blume-Jensen

In April 2018, we entered into a patent license agreement, or the Blume-Jensen License, with Peter Blume-Jensen, our Chief Executive Officer and President, that granted us an exclusive, worldwide, irrevocable, perpetual, royalty-free license under certain licensed patents for any and all purposes and uses, including without limitation and rights to sublicense through multiple tiers. Under the terms of the Blume-Jensen License, we were obligated to reimburse Dr. Blume-Jensen the sum of $150,000, which represented the parties' agreed upon estimate of unreimbursed past expenses incurred by Dr. Blume-Jensen with respect to the preparation, filing, prosecution, protection and maintenance of the licensed patents, within 30 days following the closing of an equity financing by us with gross proceeds of at least $2,000,000. Following the closing of our Series A-1 Preferred Stock financing, we paid Dr. Blume-Jensen $150,000 in October 2020 to satisfy this obligation under the Blume-Jensen License.

Series B Preferred Stock Financing

In November 2021, we entered into a Series B preferred stock purchase agreement, or the Series B Purchase Agreement, with certain investors, including beneficial owners of greater than 5% of our capital stock and affiliates of certain members of our board of directors, pursuant to which we issued and sold to such investors an aggregate of 17,521,047 shares of our Series B preferred stock, par value $0.001 per share, or Series B Preferred Stock, at a purchase price of $5.70742 per share for aggregate gross proceeds of $100.0 million.

The table below sets forth the aggregate number of shares of Series B preferred stock issued to our related parties in this financing:

Name	Series B Preferred Stock (#)	Aggregate Purchase Price ($)
Chione Limited[1]	26,281	149,997
Citadel Multi-Strategy Equities Master Fund Ltd.	2,190,131	12,499,997
Perceptive Life Sciences Master Fund, Ltd.	2,978,578	16,999,996
Entities affiliated with RA Capital Management[2]	3,504,210	19,999,998
Sands Capital Life Sciences Pulse Fund II, L.P.	2,102,526	11,999,999
Wellington Biomedical Innovation Master Investors (Cayman) I L.P.	2,190,131	12,499,997

(1) Marcin Czernik, a former member of our board of directors, is a director of Chione Limited. Chione Limited holds more than 5% of our capital stock prior to this offering.
(2) Derek DiRocco, Ph.D., a member of our board of directors, is a partner at RA Capital Management. Entities affiliated with RA Capital Management hold more than 5% of our capital stock prior to this offering.

Investors' Rights, Voting, Right of First Refusal and Co-Sale, and Management Rights Agreements

In connection with our convertible preferred stock financings, we entered into investors' rights, voting, right of first refusal and co-sale and management rights agreements containing registration rights, information rights, rights of first offer, voting rights and rights of first refusal, among other things, with certain holders of our capital stock, including Chione Limited, New Enterprise Associates 16, LP, entities affiliated with RA Capital Management, Citadel Multi-Strategy Equities Master Fund Ltd., Perceptive Life Sciences Master Fund, Ltd., Entities affiliated with RA Capital Management, Sands Capital Life Sciences Pulse Fund II, L.P., and Wellington Biomedical Innovation Master Investors (Cayman) I L.P. Marcin Czernik, a former member of our board of directors, is a director of Chione Limited. Derek DiRocco, Ph.D., a member of our board of directors, is a partner at RA Capital Management. Peter Blume-Jensen, M.D., Ph.D., our co-founder, Chief Executive Officer and President and a member of our board of directors, and Kristina Masson, Ph.D., our co-founder and Executive Vice President, Business Operations, are party to certain of these agreements in their capacity as a stockholder.

The foregoing 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 the section titled "Description of Capital Stock—Registration Rights."

Employment Arrangements

We have entered into employment agreements or offer letter agreements with certain of our executive officers. For more information regarding our employment agreements with our named executive officers, see the section titled "Executive Compensation."

Indemnification Agreements

Our amended and restated certificate of incorporation that will be in effect upon the closing of this offering will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers, employees and other agents when determined appropriate by the board.

In addition, in connection with this offering, we expect to enter into indemnification agreements with each of our directors and our executive officers prior to the closing of this offering. For more information regarding these agreements, see the section titled "Executive Compensation—Limitations on Liability and Indemnification Matters."

Related Person Transaction Policy

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. In connection with this offering, we have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions, which policy will become effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction will be a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director will not be covered by this policy. A related person will be any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present

information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct that we expect to adopt prior to the closing of this offering, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy will require that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

All of the transactions described in this section were entered into prior to the adoption of this policy. Although we have not had a written policy for the review and approval of transactions with related persons, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to a director's or officer's relationship or interest in the agreement or transaction were disclosed to our board of directors. Our board of directors took this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all our stockholders.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of September 30, 2022:

- each of our named executive officers;
- each of our directors;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC, and therefore it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. We have deemed shares of common stock subject to options that are currently exercisable or exercisable within 60 days of September 30, 2022, to be outstanding and to be beneficially owned by the person holding the option for the purpose of computing the percentage ownership of that person but have not treated them as outstanding for the purpose of computing the percentage ownership of any other person.

We have based percentage ownership of common stock before this offering on 12,934,862 shares of common stock outstanding as of September 30, 2022, which includes 11,140,262 shares of common stock resulting from the conversion of all outstanding shares of preferred stock immediately upon the closing of this offering, as if this conversion had occurred as of September 30, 2022. Percentage ownership of common stock after this offering assumes the sale of 5,900,000 shares of common stock in this offering and no exercise of the underwriters' option to purchase additional shares of common stock from us.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Acrivon Therapeutics, Inc., 480 Arsenal Way, Suite 100, Watertown, MA 02472.

	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Greater than 5% Stockholders:			
Chione Limited[1]	3,456,597	26.7%	18.4%
Entities affiliated with RA Capital Management[2]	1,421,008	11.0%	7.5%
Perceptive Life Sciences Master Fund, Ltd.[3]	1,207,858	9.3%	6.4%
Citadel Multi-Strategy Equities Master Fund Ltd.[4]	888,130	6.9%	4.7%
Wellington Biomedical Innovation Master Investors (Cayman) I L.P.[5]	888,130	6.9%	4.7%
Sands Capital Life Sciences Pulse Fund II, L.P.[6]	852,605	6.6%	4.5%
Directors and Named Executive Officers:			
Peter Blume-Jensen, M.D., Ph.D.[7]	1,387,547	10.5%	7.3%
Derek DiRocco, Ph.D.	—	—	—
Kristina Masson, Ph.D.[8]	1,387,547	10.5%	7.3%
Sharon Shacham, Ph.D., M.B.A.	—	—	—
Michael Tomsicek, M.B.A.	—	—	—
Erick Gamelin, M.D., Ph.D.[9]	45,619	*	*
Eric Devroe, Ph.D.[10]	80,790	*	*
All directors and executive officers as a group (8 persons)[11]	1,513,956	11.4%	7.9%

* Represents beneficial ownership of less than 1%.

(1) Consists of (a) 3,445,940 shares of common stock issuable upon conversion of Series A-1 Preferred Stock and (b) 10,657 shares of our common stock issuable upon conversion of Series B Preferred Stock. Chione Limited's directors, Mr. Czernik, Andreas Hadjimichael and Anastasios Nikolaou, and its sole stockholder, Wiaczeslaw Smolokowski, may be deemed to share voting and investment power and beneficial ownership of the shares held directly by Chione Limited. Chione Limited's address is Simou Menardou 5, Kifisia Court. Office 225, 6015 Larnaca, Cyprus.

(2) Consists of (a) 994,706 shares of common stock issuable upon conversion of Series B Preferred Stock held directly by RA Capital Healthcare Fund, L.P. ("RA Healthcare") and (b) 426,302 shares of common stock issuable upon conversion of Series B Preferred Stock held directly by RA Capital Nexus Fund II, L.P. ("Nexus II"). Derek DiRocco, Ph.D., a member of our board of directors, is a partner at RA Capital Management, L.P. ("RA Capital"). RA Capital is the investment manager for RA Healthcare and Nexus II. The general partner of RA Capital is RA Capital Management GP, LLC ("RA Capital GP"), of which Peter Kolchinsky and Rajeev Shah are the managing members. RA Capital, RA Capital GP, Peter Kolchinsky and Rajeev Shah may be deemed to have shared voting and investment power with respect to the shares held by RA Healthcare and Nexus II. The address of all entities and individuals referenced in this footnote is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(3) Consists of 1,207,858 shares of common stock issuable upon conversion of Series B Preferred Stock held by Wellington Biomedical Innovation Master Investors (Cayman) I L.P. ("Wellington Biomedical Fund"). Wellington Management Company LLP, a registered investment adviser under the Investment Advisers Act of 1940, as amended, is the investment adviser to Wellington Biomedical Fund, and Wellington Alternative Investments LLC is its general partner. Wellington Management Investment, Inc. is the managing member of Wellington Alternative Investments LLC. Wellington Management Company LLP is an indirect subsidiary of Wellington Management Group LLP. Wellington Management Group LLP and Wellington Management Company LLP may be deemed beneficial owners with shared voting and investment power over the shares held by Wellington Biomedical Fund. Additional information about Wellington Management Company LLP is available in its Form ADV filed with the SEC. The address of all entities referenced in this footnote is 280 Congress Street, Boston, MA 02210.

(4) Consists of 888,130 shares of common stock issuable upon conversion of Series B Preferred Stock held by Citadel Multi-Strategy Equities Master Fund Ltd ("CEMF"). Citadel Advisors LLC ("Citadel Advisors") is the portfolio manager for CEMF. Citadel Advisors Holdings LP ("CAH") is the sole member of Citadel Advisors. Citadel GP LLC ("CGP") is the general partner of CAH. Kenneth Griffin is the President and Chief Executive Officer of CGP, and 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 direct the disposition of, the shares identified above. The foregoing shall not be construed as an admission that Mr. Griffin or any of the Citadel related entities listed above is the beneficial owner of any securities referenced herein other than the securities actually owned by such person (if any). The address of Citadel Advisors LLC is 601 Lexington Avenue, New York, NY 10022.

(5) Consists of 888,130 shares of common stock issuable upon conversion of Series B Preferred Stock held by Wellington Biomedical Innovation Master Investors (Cayman) I L.P. ("Wellington Biomedical Fund"). Wellington Management Company LLP, a registered investment adviser under the Investment Advisers Act of 1940, as amended, is the investment adviser to Wellington Biomedical Fund, and Wellington Alternative Investments LLC is its general partner. Wellington Management Investment, Inc. is the managing member of Wellington Alternative Investments LLC. Wellington Management Company LLP is an indirect subsidiary of Wellington Management Group LLP. Wellington Management Group LLP and Wellington Management Company LLP may be deemed beneficial owners with shared voting and investment power over the shares held by Wellington Biomedical Fund. Additional information about Wellington Management Company LLP is available in its Form ADV filed with the SEC. The address of all entities referenced in this footnote is 280 Congress Street, Boston, MA 02210.

(6) Consists of 852,605 shares of common stock issuable upon conversion of Series B Preferred Stock. Sands Capital Life Sciences Pulse Fund II-GP, L.P. ("Pulse Fund II GP LP") is the sole general partner of Sands Capital Life Sciences Pulse Fund II, L.P. ("Pulse Fund II"), and the sole general partner of Pulse Fund II GP LP is Sands Capital Life Sciences Pulse Fund II-GP, LLC ("Pulse Fund II GP LLC"). Frank M. Sands

holds ultimate voting and investment power over the shares held directly by Pulse Fund II, Pulse Fund II GP LP, and Pulse Fund II GP LLC, and may be deemed to have beneficial ownership with respect to the shares held directly by Pulse Fund II. The address of all entities and the individual referenced in this footnote is 1000 Wilson Boulevard, Suite 3000, Arlington, VA 22209.

(7) Consists of (a) (i) 871,857 shares of common stock and (ii) 147,796 shares of common stock issuable upon the exercise of options within 60 days of September 30, 2022 held directly by Dr. Blume-Jensen and (b) (i) 293,998 shares of common stock and (ii) 73,896 shares of common stock issuable upon the exercise of options within 60 days of September 30, 2022 held directly by Dr. Blume-Jensen's spouse, Dr. Masson.

(8) Consists of (a) (i) 293,998 shares of common stock and (ii) 73,896 shares of common stock issuable upon the exercise of options within 60 days of September 30, 2022 held directly by Dr. Masson and (b) (i) 871,857 shares of common stock and (ii) 147,796 shares of common stock issuable upon the exercise of options within 60 days of September 30, 2022 held directly by Dr. Masson's spouse, Dr. Blume-Jensen.

(9) Consists of 45,619 shares of common stock issuable upon the exercise of options within 60 days of September 30, 2022.

(10) Consists of (a) 20,275 shares of common stock and (b) 60,515 shares of common stock issuable upon the exercise of options within 60 days of September 30, 2022.

(11) Consists of (a) 1,186,130 shares of common stock and (b) 327,826 shares of common stock issuable upon the exercise of options within 60 days of September 30, 2022.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock, certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws, as each will be in effect following the completion of this offering, and certain provisions of Delaware law are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the completion of this offering, our amended and restated certificate of incorporation will authorize us to issue up to 500,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share, all of which shares of preferred stock will be undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

As of June 30, 2022, we had outstanding 1,769,561 shares of common stock, held by seven stockholders of record. As of June 30, 2022, after giving effect to the conversion of all of the outstanding shares of our convertible preferred stock, including shares of our Series A-1 Preferred Stock and Series B Preferred Stock, into 11,140,262 shares of common stock, there would have been 12,909,823 shares of common stock issued and outstanding, held by 21 stockholders of record.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. The affirmative vote of holders of at least $66^{2}/_{3}\%$ of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive forum.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the right of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

As of June 30, 2022, there were 27,471,911 shares of preferred stock outstanding, consisting of 9,904,806 shares of Series A-1 convertible preferred stock and 17,567,105 shares of Series B convertible preferred stock. All currently outstanding shares of convertible preferred stock will be converted into an aggregate of 11,140,262 shares of common stock upon the closing of this offering.

Following the closing of this offering, our board of directors will have the authority under our amended and restated certificate of incorporation, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

We have no present plans to issue any shares of preferred stock following completion of this offering.

Options

As of June 30, 2022, there were options to purchase 2,072,851 shares of common stock outstanding under our 2019 Plan. For additional information regarding the terms of our 2019 Plan, see the section titled “Executive Compensation—Equity Incentive Plans.”

Registration Rights

We, the holders of our existing convertible preferred stock and certain holders of our existing common stock have entered into an amended and restated investors’ rights agreement. The registration rights provisions of this agreement provide those holders with demand, piggyback and Form S-3 registration rights with respect to the shares of common stock currently held by them and issuable to them upon conversion of our convertible preferred stock in connection with our IPO. These shares are collectively referred to herein as registrable securities.

Demand Registration Rights

At any time beginning 180 days following the effective date of the registration statement of which this prospectus is a part, the holders of a majority of registrable securities then outstanding have the right to demand that we file a registration statement covering registrable securities then outstanding having an aggregate offering price in excess of $15.0 million, net of certain selling expenses. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to effect the registration as soon as practicable, but in any event no later than 60 days after the receipt of such request. An aggregate of 11,476,837 shares of common stock will be entitled to these demand registration rights.

Piggyback Registration Rights

If we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, the holders of registrable securities will each be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances. An aggregate of 11,476,837 shares of common stock will be entitled to these piggyback registration rights.

Registration on Form S-3

At any time after we become eligible to file a registration statement on Form S-3, the holders of at least 30% of the registrable securities then outstanding will be entitled to request to have such shares registered by us on a Form S-3 registration statement. These Form S-3 registration rights are subject to other specified conditions and limitations, including the condition that the anticipated aggregate offering price, net of certain selling expenses, is at least $5.0 million. Upon receipt of this request, the holders of registrable securities will each be entitled to participate in this registration. An aggregate of 11,476,837 shares of common stock will be entitled to these Form S-3 registration rights.

Expenses of Registration

We are required to pay all expenses, including fees and expenses of one counsel to represent the selling stockholders (up to $50,000 total), relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, stock transfer taxes and any additional fees of counsel for the selling stockholders, subject to specified conditions and limitations. We are not required to pay registration expenses if a demand registration request is withdrawn at the request of a majority of holders of registrable securities to be registered, unless holders of a majority of the registrable securities agree to forfeit their right to one demand registration.

The amended and restated investors' rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the applicable registration statement attributable to us, and the selling stockholders are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them, subject to certain limitations.

Termination of Registration Rights

The registration rights granted under the investors' rights agreement will terminate with respect to any particular stockholder upon the earlier of (a) the closing of a deemed liquidation event, as defined in our certificate of incorporation, (b) the fifth anniversary of the closing of this offering and (c) with respect to each stockholder, at such time such stockholder is able to sell all of its shares without limitation pursuant to Rule 144 or another similar exemption under the Securities Act during a three-month period without registration.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that 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 began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66⅔% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation or of any direct or indirect majority-owned subsidiary involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or any such subsidiary beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our amended and restated certificate of incorporation to be in effect upon the completion of this offering, or our restated certificate, will provide for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our restated certificate and our amended and restated bylaws to be effective upon the completion of this offering, or our restated bylaws, will also provide that directors may be removed by the stockholders only for cause upon the vote of 66⅔% or more of our outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board and subject to the rights of any series of then-outstanding preferred stock, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Under our restated certificate of incorporation and amended and restated bylaws our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Our restated certificate and restated bylaws will also provide that all stockholder actions must be effected at a duly called meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. Our restated bylaws will also provide that only our Chairman of the board, Chief Executive Officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our restated bylaws will also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and will specify requirements as to the form and content of a stockholder's notice.

Our restated certificate and restated bylaws will provide that the stockholders cannot amend many of the provisions described above except by a vote of 66⅔% or more of our outstanding common stock.

As described in "—Preferred Stock" above, our restated certificate will give our board of directors the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the state of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate, or our amended and restated bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will also 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 exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions

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

Our amended and restated certificate of incorporation will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

Listing

Our common stock has been approved for listing on the Nasdaq Global Market under the trading symbol "ACRV."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common stock. 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, 2022, upon the closing of this offering and assuming no exercise of the underwriters' option to purchase additional shares, 18,809,823 shares of common stock will be outstanding, assuming no outstanding options are exercised. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act. The remaining 12,909,823 shares of common stock held by existing stockholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 promulgated under the Securities Act or another available exemption. We expect that substantially all of these shares held by existing stockholders will be subject to the lock-up period under the lock-up agreements described below.

Rule 144

In general, non-affiliate persons who have beneficially owned restricted shares of our common stock for at least six months, and any of our affiliates who owns either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of any prior owner other than one of our affiliates (subject to certain exceptions);
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of restricted securities without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting. Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 200,000 shares immediately after the completion of this offering based on the number of shares outstanding as of June 30, 2022; or

- the average weekly trading volume of our common stock on the stock exchange on which our shares are listed during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

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 date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section titled "Underwriting" and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity plans. We expect to file the registration statement covering shares offered pursuant to our stock plans as soon as practicable after the closing of this offering, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144 and expiration or release from the terms of the lock-up agreements described above.

Lock-Up Agreements

We, our executive officers and directors and substantially all of the holders of our common stock outstanding on the date of this prospectus have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our shares of common stock, any options or warrants to purchase shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock, without the prior written consent of Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC for a period of 180 days from the date of this prospectus.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into an agreement with the holders of our preferred stock that contains market stand-off provisions imposing restrictions on the ability of such security holders to sell or otherwise transfer or dispose of any registrable securities for a period of 180 days following the date of this prospectus.

Registration Rights

Upon the closing of this offering, the holders of 11,476,837 shares of our common stock, including common stock issuable upon the conversion of our convertible preferred stock, or their transferees, will be entitled to specified rights with respect to the registration of their registrable shares under the Securities Act, subject to certain limitations and the expiration, waiver or termination of the lock-up agreements. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon effectiveness of the registration. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following summary describes certain material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the, ownership and disposition of our common stock acquired in this offering. The summary below is based upon the provisions of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and Treasury Regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested and will not request a ruling from the U.S. Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions. This discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This summary is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, and does not address non-U.S. or U.S. state and local consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address U.S. federal tax consequences (such as gift and estate taxes) other than income taxes. This summary also does not address the alternative minimum tax, the Medicare contribution tax on net investment income, the special tax accounting rules under Section 451(b) of the Code, or the rules regarding qualified small business stock within the meaning of Section 1202 of the Code. Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code, such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, corporations organized outside of the United States, any state thereof and the District of Columbia that are nonetheless treated as U.S. taxpayers for U.S. federal income tax purposes, persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment or other risk reduction strategy, persons who acquire our common stock through the exercise of an option or otherwise as compensation, persons that hold more than 5% of our outstanding common stock, directly or indirectly during the applicable testing period (except to the extent specifically set forth below), "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by one or more qualified foreign pension funds, persons deemed to sell our common stock under the constructive sale provisions of the Code, partnerships and other pass-through entities or arrangements, and investors in such pass-through entities or arrangements. Non-U.S. Holders are urged to consult their tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership (or entity or arrangement treated as partnership for U.S. federal income tax purposes) will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PERSONS CONSIDERING THE PURCHASE OF OUR COMMON STOCK PURSUANT TO THIS OFFERING SHOULD CONSULT THEIR TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME, ESTATE AND OTHER TAX CONSEQUENCES OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK IN LIGHT OF THEIR PARTICULAR SITUATIONS AS WELL AS ANY CONSEQUENCES ARISING UNDER THE LAWS OF ANY OTHER TAXING JURISDICTION, INCLUDING ANY STATE, LOCAL OR NON-U.S. TAX CONSEQUENCES.

For purposes of this discussion, the term "Non-U.S. Holder" means a beneficial owner of our common stock (other than a partnership or other entity or arrangement treated as a partnership for U.S. federal income tax purposes regardless of its place of organization or formation) that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;

- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

Distributions, if any, made on our common stock to a Non-U.S. Holder to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. federal income tax purposes. If a distribution exceeds our current and accumulated earnings and profits, the excess will constitute a tax-free return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any remaining excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, dividends paid to a Non-U.S. Holder 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, provided the Non-U.S. Holder furnishes a properly executed IRS Form W-8BEN (in the case of individuals) or W-8BEN-E (in the case of entities), or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under such income tax treaty). This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically.

Dividends paid to a Non-U.S. Holder that are treated as effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), are generally exempt from the 30% U.S. federal withholding tax described above if the Non-U.S. Holder delivers to us (or, if stock is held through a financial institution or other agent, to such agent) a properly executed IRS Form W-8ECI, stating that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net-income basis at the regular rates applicable to U.S. persons (as defined in the Code). A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

If a Non-U.S. Holder is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty and does not timely file the required certification, the Non-U.S. Holder may be able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaties.

Sale or Other Taxable Disposition

Subject to the discussions below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain recognized on a sale or other disposition of our common stock unless:

- the gain is effectively connected with a trade or business of such Non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such holder maintains in the United States);
- the Non-U.S. Holder is a nonresident alien individual and is treated, for U.S. federal income tax purposes, as present in the United States for a period or periods aggregating to 183 or more days in the taxable year of the disposition and certain other conditions are met; or
- we are, or have been at any time during the five-year period preceding such 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 (as defined under applicable Treasury Regulations) and the Non-U.S. Holder held no more than 5% of our outstanding common stock, directly or indirectly, 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 net gain derived from the disposition of our common stock generally in the same manner as gain that is effectively connected with the conduct of a trade or business in the United States, at the U.S. federal income tax rates applicable to U.S. persons (as defined in the Code), except that the branch profits tax generally will not apply. Generally, a corporation is a "United States real property holding corporation" if the fair market value of its "United States real property interests" 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 believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rule described above.

A Non-U.S. Holder described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates, and corporate Non-U.S. Holders described in the first bullet point above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

Gain described in second bullet point above will be subject to U.S. federal income tax at a flat 30% rate, which gain may be offset by certain U.S.-source capital losses (even though the Non-U.S. Holder 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.

Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Information Reporting Requirements and Backup Withholding

Generally, we must report annually information to the IRS and to each Non-U.S. Holder the gross amount of the distributions we pay on our common stock (even if the payments are exempt from withholding), including the amount of any such distributions, the name and address of the recipient and the amount, if any, of tax withheld.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding (currently at a rate of 24%). U.S. backup withholding generally will not apply to a Non-U.S. Holder

who provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-ECI (as applicable), or otherwise establishes an exemption. Notwithstanding the foregoing, backup withholding may apply if the withholding agent has actual knowledge, or reason to know, that the holder is a U.S. person (as defined in the Code) who is not an exempt recipient.

U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock by a Non-U.S. Holder effected by or through a U.S. office of any broker, U.S. or foreign, unless the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E or otherwise meets documentary evidence requirements for establishing non-U.S. person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements 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 non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Non-U.S. Holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities of the country in which the Non-U.S. Holder's resides or is incorporated. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be refunded or credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, provided that the required information is timely furnished to the IRS.

Foreign Accounts

Sections 1471 through 1474 of the Code (commonly referred to as FATCA) impose a U.S. federal withholding tax of 30% on certain payments, made to a non-U.S. financial institution (as specifically defined by applicable rules) unless (i) if the non-U.S. entity is a "foreign financial institution," such non-U.S. entity undertakes certain due diligence, reporting, withholding and certification obligations, (ii) if the non-U.S. entity is not a "foreign financial institution," such non-U.S. entity identifies certain of its U.S. investors, if any or (iii) the non-U.S. entity is otherwise exempt under FATCA. FATCA currently applies dividends paid on our common stock. FATCA also applies to gross proceeds from the sale or other disposition of our common stock, but the U.S. Treasury released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In the preamble to such proposed regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. 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 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.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT OR PROPOSED CHANGE IN APPLICABLE LAW.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC and Piper Sandler & Co. are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares of common stock indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	
Jefferies LLC	
Cowen and Company, LLC	
Piper Sandler & Co.	
Total	5,900,000

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $ per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 885,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total 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 up to an additional 885,000 shares of common stock.

		Total	
	Per Share	No Exercise	Full Exercise
Public offering price	$	$	$
Underwriting discounts and commissions	$	$	$
Proceeds, before expenses, to us	$	$	$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $2.9 million. We have agreed to reimburse the underwriters for expenses of up to $35,000 relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc., compliance with state securities or "blue sky" laws.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

Our common stock has been approved for listing on the Nasdaq Global Market under the trading symbol "ACRV."

We and all of our directors and officers and the holders of all of our outstanding common stock, stock options and other securities convertible into, exercisable or exchangeable for our common stock outstanding immediately prior to the closing of this offering have agreed that, without the prior written consent of Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus, or the restricted period:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock.

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of the representatives on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph to do not apply to our directors, officers and securityholders with respect to:

- transactions relating to shares of our common stock or other securities acquired in this offering or in open market transactions after the completion of this offering, provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of our common stock shall be voluntarily made during the restricted period in connection with subsequent sales of our common stock or other securities acquired in this offering or in such open market transactions;
- transfers or distributions of shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock (i) as a bona fide gift or charitable contribution, (ii) by will or intestacy or to any immediate family or to a trust for the direct or indirect benefit of the stockholder and/or any immediate family, (iii) to limited partners, members, stockholders or holders of similar equity interests in the stockholder or (iv) if the stockholder is a corporation, to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate (as defined in Rule 405 promulgated under the Securities Act) of the stockholder, or to any investment fund or other entity controlled or managed by such stockholder or affiliates of such stockholder; provided that (A) each transferee, donee or distributee shall sign and deliver a lock up agreement and (B) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of our common stock, shall be required or shall be voluntarily made during the restricted period, and provided further that any such transfer shall not involve a disposition for value;
- transfers of our common stock or any security convertible into or exercisable or exchangeable for our common stock by operation of law pursuant to a qualified domestic order or other court order or in

connection with a divorce settlement; provided that (i) any filing under Section 16(a) of the Exchange Act made during the restricted period shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described in this clause and (B) no securities were sold by such stockholder, and (ii) such stockholder does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period;

- the receipt by such stockholder from us of shares of our common stock upon the transfer or disposition of shares of our common stock or any securities convertible into our common stock to us upon a vesting or settlement event of our securities or vesting of restricted stock unit awards or upon the exercise of options to purchase our securities on a "cashless" or "net exercise" basis, in each case pursuant to any equity incentive plan of us described in this prospectus and to the extent permitted by the instruments representing such restricted stock unit awards or options outstanding as of the date of this prospectus (and solely to cover withholding tax obligations in connection with such transaction and any transfer to us for the payment of taxes as a result of such transaction), provided that (i) the shares received upon exercise or settlement of the option are subject to the terms of this agreement, (ii) no public disclosure or filing under Section 16(a) of the Exchange Act shall be voluntarily made during the restricted period and (iii) to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers in this clause, it shall clearly indicate that (A) the filing relates to the circumstances described in this clause, including that the securities remain subject to the terms of this agreement and (B) no securities were sold by such stockholder other than pursuant to this clause;
- transfers to us to the extent required in order to satisfy the exercise price and/or any income, employment tax withholding and remittance obligations upon the vesting or exercise of an option or other award granted under an equity incentive plan or share purchase plan of us described in this prospectus or the conversion or exercise of a warrant of us described in this prospectus; provided that (i) any filing under Section 16(a) of the Exchange Act made during the restricted period shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described in this paragraph and (B) no securities were sold by such stockholder, and (ii) such stockholder does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period;
- transfers to us in connection with the repurchase of our common stock in connection with the termination of such stockholder's employment with us pursuant to contractual agreements with us as in effect as of the date of this prospectus, provided that no public disclosure or filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the restricted period;
- the conversion of the outstanding preferred stock of us described in this prospectus into shares of our common stock of us, provided that such shares of our common stock remain subject to the terms of the lock-up agreement;
- facilitating the establishment of a trading plan on behalf of a stockholder, officer or director of us pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of our common stock, provided that (i) such plan does not provide for the transfer of our common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of such stockholder or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of our common stock may be made under such plan during the restricted period; or
- transfers pursuant to a bona fide third-party tender offer for all outstanding our common stock or securities convertible into or exchangeable for our common stock of us, merger, consolidation or other similar transaction approved by our board of directors and made to all holders of our securities involving a change of control of us (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which such stockholder may agree to transfer, sell, tender or otherwise dispose of our common stock or other such securities in connection with such transaction, or vote any our common stock or other such securities in favor of any such transaction); provided that in

the event that such tender offer, merger, consolidation or other such transaction is not completed, such securities held by such stockholder shall remain subject to the provisions of the lock-up agreement.

The restrictions on transfers or other dispositions by us described above do not apply to:

- the shares to be sold in this offering;
- the issuance by us of shares of common stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof as described in this prospectus; or
- facilitating the establishment of a trading plan on behalf of one of our stockholders, officers or directors pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the option to purchase additional shares described above. The underwriters can close out a covered short sale by exercising such option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under such option. The underwriters may also sell shares in excess of such option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives. Among the factors to be considered in determining the initial public offering price are our future prospects and those of our industry in general, our results of operations and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) 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.

European Economic Area

In relation to each Member State of the European Economic Area and the United Kingdom, each, a Relevant State, no securities have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; 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 our representatives 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 any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

United Kingdom

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, or the FSMA) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended), or the FIEL, has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

For Qualified Institutional Investors, or QII

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "QII only private placement" or a "QII only secondary distribution" (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "small number private

placement" or a "small number private secondary distribution" (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

Hong Kong

Shares of our common stock may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation, or document relating to shares of our common stock may be issued or may be in the possession of any person for the purpose of issue (in each case 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 in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of our common stock may not be circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where shares of our common stock are subscribed or purchased under Section 275 by a relevant person which is: (i) a corporation (which is not an accredited investor) 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 (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures, and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired shares of our common stock under Section 275 except: (a) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (b) where no consideration is given for the transfer; or (c) by operation of law.

Switzerland

The shares of common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document

nor any other offering or marketing material relating to the offering, us, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Cooley LLP, New York, New York. Certain legal matters will be passed upon for the underwriters by Goodwin Procter LLP, New York, New York.

EXPERTS

The financial statements as of December 31, 2021 and 2020 and for each of the years then ended, included in this prospectus have been so included in reliance on the report (which contains an emphasis of matter paragraph regarding the Company's significant operating losses and negative cash flows from operations since its inception, and management's evaluation of the events and conditions and management's plans to mitigate these matters, as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at *www.sec.gov*. Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available at *www.sec.gov*.

We also maintain a website at *www.acrivon.com*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements for the Years Ended December 31, 2021 and 2020:

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Acrivon Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' deficit and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements 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 consolidated financial statements are free of material misstatement, whether due to error or fraud.

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

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant operating losses and negative cash flows from operations since its inception. Management's evaluation of the events and conditions and management's plans to mitigate these matters are also described in Note 1.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
August 12, 2022, except for the effects of the reverse stock split discussed in Note 17 to the consolidated financial statements, as to which the date is November 3, 2022

We have served as the Company's auditor since 2022.

ACRIVON THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 99,603	$ 1,583
Prepaid expenses and other current assets	805	136
Total current assets	100,408	1,719
Property and equipment, net	290	59
Operating lease right-of-use assets	5,501	—
Restricted cash	388	407
Total assets	$106,587	$ 2,185
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 964	$ 136
Accrued expenses and other current liabilities	1,286	477
Operating lease liabilities, current	664	—
Total current liabilities	2,914	613
Operating lease liabilities, long-term	4,964	—
Preferred stock tranche rights	—	318
Total liabilities	7,878	931
Commitments and contingencies (Note 14)		
Series A-1 convertible preferred stock, par value $0.001; 9,904,806 and 9,685,508 shares authorized as of December 31, 2021 and 2020, respectively; 9,904,806 and 4,422,350 shares issued and outstanding as of December 31, 2021 and 2020, respectively; liquidation preference of $22.6 million as of December 31, 2021.	22,502	9,667
Series B convertible preferred stock, par value $0.001; 17,567,105 and 0 shares authorized, issued and outstanding as of December 31, 2021 and 2020, respectively; liquidation preference of $100.3 million as of December 31, 2021.	100,016	—
Stockholders' deficit:		
Common stock, par value $0.001; 40,013,683 and 20,000,000 shares authorized as of December 31, 2021 and 2020, respectively; 1,769,561 and 1,432,480 shares issued and outstanding as of December 31, 2021 and 2020, respectively.	2	1
Additional paid-in capital	1,054	208
Accumulated deficit	(24,865)	(8,622)
Total stockholders' deficit	(23,809)	(8,413)
Total liabilities, convertible preferred stock and stockholders' deficit	$106,587	$ 2,185

The accompanying notes are an integral part of these consolidated financial statements.

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

	Year Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	$ 13,718	$ 1,870
General and administrative	2,466	1,298
Total operating expenses	16,184	3,168
Loss from operations	(16,184)	(3,168)
Other income (expense):		
Other income, net	21	32
Change in fair value of convertible notes	—	(2,099)
Change in fair value of preferred stock tranche rights	(50)	(71)
Change in fair value of anti-dilution right	(30)	—
Total other expense, net	(59)	(2,138)
Net loss and comprehensive loss	$ (16,243)	$ (5,306)
Net loss per share—basic and diluted	$ (9.32)	$ (3.70)
Weighted-average common stock outstanding—basic and diluted	1,743,382	1,432,480

The accompanying notes are an integral part of these consolidated financial statements.

ACRIVON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	—	$ —	1,432,480	$ 1	$ 205	$ (3,316)	$ (3,110)
Issuance of Series A-1 convertible preferred stock, net of preferred stock tranche rights and issuance costs of $247 and $169, respectively	1,315,789	2,584	—	—	—	—	—
Issuance of Series A-1 convertible preferred stock related to conversion of convertible notes	3,106,561	7,083	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	(5,306)	(5,306)
Balance at December 31, 2020	4,422,350	$ 9,667	1,432,480	$ 1	$ 208	$ (8,622)	$ (8,413)
Issuance of common stock related to license agreement with Eli Lilly	—	—	336,575	1	348	—	349
Exercise of common stock options	—	—	506	—	1	—	1
Issuance of Series A-1 convertible preferred stock, net of issuance costs of $33	5,321,132	12,467	—	—	—	—	—
Issuance of Series A-1 convertible preferred stock related to settlement of preferred stock tranche rights	161,324	368	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $247	17,521,047	99,753	—	—	—	—	—
Issuance of Series B convertible preferred stock related to settlement of anti-dilution right	46,058	263	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	497	—	497
Net loss	—	—	—	—	—	(16,243)	(16,243)
Balance at December 31, 2021	27,471,911	$ 122,518	1,769,561	$ 2	$ 1,054	$ (24,865)	$ (23,809)

The accompanying notes are an integral part of these consolidated financial statements.

ACRIVON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31, 2021	2020
Cash flows from operating activities:		
Net loss	$ (16,243)	$ (5,306)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	37	13
Stock-based compensation expense	497	3
Non-cash lease expense	795	—
License agreement paid for with common stock	349	—
Anti-dilution right assumed with license agreement	233	—
Change in fair value of convertible notes	—	2,099
Change in fair value of preferred stock tranche rights	50	71
Change in fair value of anti-dilution right	30	—
Gain upon extinguishment of PPP loan	(58)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(764)	(117)
Accounts payable	798	81
Accrued expenses and other liabilities	866	353
Operating lease liabilities	(572)	—
Net cash used in operating activities	(13,982)	(2,803)
Cash flows from investing activities:		
Purchases of property and equipment	(238)	(15)
Net cash used in investing activities	(238)	(15)
Cash flows from financing activities:		
Proceeds from issuance of Series A-1 preferred stock and preferred stock tranche obligations in first closing, net of issuance costs	—	2,831
Proceeds from issuance of PPP loan	—	58
Proceeds from issuance of Series A-1 preferred stock in second and third closings, net of issuance costs	12,467	—
Proceeds from issuance of Series B preferred stock, net of issuance costs and settlement of anti-dilution right	99,753	—
Proceeds from exercise of stock options	1	—
Net cash provided by financing activities	112,221	2,889
Net increase in cash, cash equivalents, and restricted cash	98,001	71
Cash, cash equivalents and restricted cash at beginning of period	1,990	1,919
Cash, cash equivalents and restricted cash at end of period	$ 99,991	$ 1,990
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of convertible notes recognized as Series A-1 preferred stock upon conversion	$ —	$ 7,083
Fair value of preferred stock tranche rights	—	247
Fair value of preferred stock tranche rights recognized as Series A-1 preferred stock upon issuance of milestone shares	368	—
Fair value of anti-dilution right recognized as Series B preferred stock upon issuance of anti-dilution shares	263	—
Purchases of property and equipment included in accounts payable	30	—
Supplemental cash flow information:		
Right-of-use assets obtained in exchange for operating lease liability	6,200	—
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 99,603	$ 1,583
Restricted cash	388	407
Total cash, cash equivalents, and restricted cash	$ 99,991	$ 1,990

The accompanying notes are an integral part of these consolidated financial statements.

ACRIVON THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business

Acrivon Therapeutics, Inc., (the "Company") is a clinical stage biopharmaceutical company developing oncology medicines that the Company matches to patients whose tumors are predicted to be sensitive to each specific medicine by utilizing its proteomics-based patient responder identification platform. The Company's pipeline includes the Phase 2 lead program, ACR-368, referred to as prexasertib, a targeted oncology asset, as well as preclinical stage pipeline programs targeting critical nodes in the DNA Damage Response and cell cycle regulation pathways, including WEE1, a protein kinase, and PKMYT1, a closely related protein serine/threonine kinase.

The Company was incorporated in March 2018 under the laws of the state of Delaware, and its principal offices are in Watertown, Massachusetts. Also in March 2018, the Company formed Acrivon AB, a wholly-owned subsidiary of the Company, established in Lund, Sweden. In December 2021, the Company formed Acrivon Securities Corporation, a wholly-owned subsidiary, established in Massachusetts.

Liquidity

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying consolidated financial statements were issued.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering drug candidates, research and development activities for ACR-368 and other compounds, establishing arrangements with third parties for the manufacture of its drug candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future.

Since its inception, the Company has funded its operations primarily with proceeds from the sales of shares of its convertible preferred stock and the issuance of convertible notes. The Company has incurred recurring losses since its inception, including net losses of $16.2 million and $5.3 million for the years ended December 31, 2021, and 2020, respectively. As of December 31, 2021, the Company had an accumulated deficit of $24.9 million. To date the Company has not generated any revenues and expects to continue generating operating losses for the foreseeable future as it continues to expand its research and development efforts.

The Company expects that its existing cash and cash equivalents of $99.6 million as of December 31, 2021 will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the date these consolidated financial statements were issued.

The Company will need additional funding to support its planned operating activities. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all. If the Company is unable to obtain sufficient funding, it could be required to delay its development efforts, limit activities and reduce research and development costs, which could adversely affect its business prospects.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. Immediately prior to the closing of a qualifying public offering on specified terms, the Company's outstanding convertible preferred stock will convert into common stock (see Note 9).

In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, government or private-party grants, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or rights of the Company's stockholders.

If the Company is unable to obtain sufficient capital, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

COVID-19 Considerations

In March 2020, the World Health Organization declared the outbreak of the novel coronavirus, COVID-19, a pandemic. The pandemic has resulted in the closing of borders, enhanced health screenings, health care service preparation and delivery, quarantines, cancellations, disruptions to supply chains, as well as general concern and uncertainty. The Company cannot predict the future progression or full impact of the outbreak and its effects on the Company's business and operations. Additionally, COVID-19 has resulted in substantial market volatility and may result in a significant economic downturn. The Company will continue to actively monitor the current international and domestic impacts of and responses to COVID-19 and its related risks. The Company considered the potential effects of the COVID-19 pandemic on its financial statements and noted that there is no material effect on the consolidated financial statements as of December 31, 2021 and 2020.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

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

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses, and the valuations of common stock, stock-based awards, preferred stock tranche rights, convertible notes and anti-dilution right. The Company bases its estimates on historical experience when available, known trends and other market specific data, or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company's focus is the research and development of precision oncology therapies. The Company's chief operating decision maker, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. As the Company has one reportable segment, all required segment financial information is presented in the consolidated financial statements. As of December 31, 2021, the majority of the Company's long-lived assets are held in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include standard checking accounts and amounts held in money market funds. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits.

Restricted Cash

Cash accounts with any type of restriction are classified as restricted cash. The Company has restricted cash deposits with a bank, which serve as collateral for a letter of credit issued to the landlord of the Company's leased facility for a security deposit. The Company classified this amount as restricted cash in the accompanying consolidated balance sheets within non-current assets based on the release date of restrictions.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. There were no deferred offering costs capitalized as of December 31, 2021 and 2020.

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company has not experienced any credit losses on its cash or cash equivalents. The Company maintains its cash and cash equivalents at a high-quality financial institution. Management believes that such funds are not exposed to any significant credit or concentration risk.

The Company is dependent on third-party contract research organizations ("CROs") and contract manufacturing organizations to supply certain intellectual property and services for research activities in its drug candidates. In particular, the Company relies and expects to continue to rely on a small number of these organizations to supply it with its requirements for key raw materials related to these programs. These drug candidates could be adversely affected by a significant interruption in the supply of key raw materials. Additionally, the Company relies on a single companion diagnostic collaborator to perform ACR-368 OncoSignature tests in the Company's clinical trials (see Note 17).

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2021 and 2020, there was no difference between net loss and comprehensive loss.

Fair Value Measurements

ASC Topic 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 among the following:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

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. The Company's convertible notes, preferred stock tranche rights and anti-dilution right were carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above.

Property and Equipment, net

Property and equipment are stated at cost, less accumulated depreciation. Costs of major additions and betterments are capitalized. Maintenance and repairs which do not improve or extend the life of the respective assets are charged to expense as incurred. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from five to seven years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. The Company had no leasehold improvements as of December 31, 2021 and 2020. When an item is sold or retired, the costs and related accumulated depreciation are eliminated, and the resulting gain or loss, if any, is credited or charged to the consolidated statement of operations and comprehensive loss. Property and equipment to be disposed of are carried at fair value less costs to sell. The estimated useful lives of the Company's property and equipment are as follows:

	Estimated Useful Life (in Years)
Laboratory equipment and computer equipment	5 years
Furniture	5-7 years
Leasehold improvements	Lesser of asset useful life or lease term

Impairment of Long-Lived Assets

The Company recognizes an impairment loss in loss from operations only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and in such case, measures an impairment loss as the difference between the carrying amount and the fair value of the asset.

The Company tests long-lived assets to be held and used, including property and equipment and operating lease right-of-use ("ROU") assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of assets or asset groups may not be fully recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their fair values. The Company has not recognized any impairment losses during the years ended December 31, 2021 and 2020.

Research and Development Expenses

Research and development costs include (i) employee-related expenses, including salaries, benefits, and stock-based compensation expense; (ii) external research and development expenses incurred under arrangements with third parties, such as CRO agreements and consultants; (iii) costs associated with preclinical activities; and (iv) lab supplies, lab expenses and an allocation of rent, depreciation, and infrastructure. Costs incurred in connection with research and development activities are expensed as incurred.

The Company enters into various consulting, research, and other agreements with commercial firms, researchers, universities and other external parties for the provision of goods and services. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred.

Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the Company's clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable. The Company monitors each of these factors and adjusts estimates accordingly. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

Asset Acquisitions and Acquired In-Process Research and Development Expenses

The Company accounts for acquisitions of assets or a group of assets that do not meet the definition of a business as asset acquisitions based on the cost to acquire the asset or group of assets, which include certain transaction costs. In an asset acquisition, the cost to acquire is allocated to the identifiable assets acquired and liabilities assumed based on their relative fair values as of the acquisition date. No goodwill is recorded in an asset acquisition. Assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in process research and development ("IPR&D"). Acquired IPR&D that has no alternative future use as of the acquisition date is recognized as research and development expense as of the acquisition date. The Company will recognize additional research and development expenses in the future if and when the Company becomes obligated to make contingent milestone payments under the terms of the agreements by which it acquired the IPR&D assets.

Contingent consideration in asset acquisitions is measured and recognized when payment becomes probable and reasonably estimable. Subsequent changes in the accrued amount of contingent consideration are measured

and recognized at the end of each reporting period and upon settlement as an adjustment to the cost basis of the acquired asset or group of assets, or, if related to IPR&D with no alternative future use, charged to expense. For the year ended December 31, 2021, the Company recognized $5.5 million of IPR&D expense in connection with the consideration due under the Lilly Agreement (see Note 7), included within research and development expense.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Company's consolidated statements of operations and comprehensive loss.

Foreign Currency Transactions

The functional currency for the Company's wholly-owned foreign subsidiary, Acrivon AB, is the United States dollar. All foreign currency transaction gains and losses are recognized in the consolidated statements of operations and comprehensive loss through other income (expense). The Company has not recognized material currency transaction gains or losses during the years ended December 31, 2021 and 2020.

Leases

Prior to January 1, 2021, the Company accounted for leases in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 840, *Leases* ("ASC 840"). 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 escalations, on a straight-line basis over the lease term.

Effective on January 1, 2021, the Company accounts for leases in accordance with ASU No. 2016-02, *Leases*, as subsequently amended (collectively, "ASC 842"). In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a ROU asset and a lease liability on the consolidated balance sheets for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less, but payments are recognized as expense on a straight-line basis over the lease term.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Finance and operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the

straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated into (i) a portion that is recorded as interest expense using the effective interest method and (ii) a portion that reduces the finance liability associated with the lease.

In addition, the Company examines other contracts with suppliers, vendors and outside parties to identify whether such contracts contain an embedded lease and, as applicable, records such embedded leases in accordance with ASC 842.

Convertible Preferred Stock

The Company's convertible preferred stock is classified as temporary equity in the accompanying consolidated balance sheets and excluded from stockholders' deficit as the potential redemption of such stock is outside the Company's control and would require the redemption of the then-outstanding convertible preferred stock. The convertible preferred stock is not redeemable except for in the event of a liquidation, dissolution, or winding up of the Company (see Note 9). Costs incurred in connection with the issuance of convertible preferred stock, as well as the recognition of the preferred stock tranche liability, are recorded as a reduction of gross proceeds from issuance. The Company does not accrete the carrying values of the preferred stock to the redemption values since the occurrence of these events was not considered probable as of December 31, 2021 and 2020. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that these events will occur.

Stock-Based Compensation

The Company accounts for all share-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value, based on the date of the grant, and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company's share-based payments include stock options and grants of common stock. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. The Company adopted ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07") at inception of the 2019 Stock Incentive Plan, prior to the issuance of any stock option grants. The measurement date for non-employee awards is the date of grant, and stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis. The Company accounts for forfeitures as they occur. Stock-based compensation expense is classified in the accompanying consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients service payments are classified.

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. The Company's board of directors determines the fair value of the Company's common stock, taking into consideration its most recently available third-party valuations of common stock and as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the grant date. The Company has historically been a private company and lacks company-specific historical and implied volatility information. The Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of representative companies and 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 has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately

equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's convertible preferred stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. Net loss attributable to common stockholders and participating preferred shares are 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 in which a net loss is recorded.

Diluted net loss 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 shares included in the computation of diluted net loss per share gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and preferred stock.

Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. 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 antidilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2021 and 2020.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or the Company's tax returns. Under this method, deferred tax assets and liabilities are determined based on the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements by prescribing a "more likely than not" threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. There are no unrecognized tax benefits included in the Company's consolidated balance sheets as of December 31, 2021 and 2020. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. The Company has not recognized interest or penalties in its consolidated statements of operations and comprehensive loss since inception.

Recently Adopted Accounting Pronouncements

ASU No. 2016-02, Leases

In February 2016, the FASB issued ASC 842, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors), and replaces the existing guidance in ASC 840.

The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine the recognition pattern of lease expense over the term of the lease. In addition, a lessee is required to record (i) a right-of-use asset and a lease liability on its balance sheets for all leases with accounting lease terms of more than 12 months regardless of whether it is an operating or financing lease and (ii) lease expense in its consolidated statements of operations and comprehensive loss for operating leases and amortization and interest expense in its consolidated statements of operations and comprehensive loss for financing leases. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases under ASC 840. In July 2018, the FASB issued ASU No. 2018-11, *Leases* (Topic 842), which added an optional transition method that allows companies to adopt the standard as of the beginning of the year of adoption as opposed to the earliest comparative period presented. This guidance is effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early application is permitted.

The Company early adopted ASC 842, with an effective date of January 1, 2021, using the modified retrospective transition approach which uses the effective date as the date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840. 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.

Upon its adoption of ASC 842 on January 1, 2021, the Company recorded a lease liability and its corresponding ROU asset 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 $0.4 million and ROU assets of $0.4 million.

ASU No. 2020-06, Debt

On January 1, 2021, the Company early adopted ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. Specifically, ASU 2020-06 simplifies accounting for the issuance of convertible instruments by removing major separation models required under current U.S. GAAP. In addition, the ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and simplifies the diluted earnings per share calculation in certain areas. The adoption of this standard did not have a material effect on the Company's consolidated financial statements.

ASU No. 2020-10, Codification Improvements

In October 2020, the FASB issued ASU No. 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company adopted this accounting standard as of January 1, 2021 with no material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

Emerging Growth Company

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company has elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. As a result of this election, the Company's financial statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

ASU 2019-12, Simplifying the Accounting for Income Tax

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Tax* ("ASU 2019-12"). The standard contains several provisions that reduce financial statement complexity including removing the exception to the incremental approach for intra-period tax expense allocation when a company has a loss from continuing operations and income from other items not included in continuing operations. The new guidance is effective for the year beginning January 1, 2022, with optional adoption prior to the effective date. The Company does not expect that the new standard will have a material impact on the Company's consolidated financial statements.

3. Fair Value Measurement

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

		Fair Value Measurements at December 31, 2021 Using:		
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$79,000	$79,000	$ —	$ —
Total assets	$79,000	$79,000	$ —	$ —

		Fair Value Measurements at December 31, 2020 Using:		
	Total	Level 1	Level 2	Level 3
Liabilities:				
Preferred stock tranche rights	$ 318	$ —	$ —	$ 318
Total liabilities	$ 318	$ —	$ —	$ 318

As of December 31, 2021, the Company's cash equivalents consisted of money market funds, classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment. As of December 31, 2020, the Company had Level 3 financial liabilities that were measured at fair value on a recurring basis. The Company's preferred stock tranche rights, convertible notes and anti-dilution right were carried at fair value determined using Level 3 inputs in the fair value hierarchy. As of December 31, 2021, the preferred stock tranche rights, convertible notes and anti-dilution right have been satisfied, and as such, there are no liabilities recorded as of December 31, 2021.

During the years ended December 31, 2021 and 2020, there were no transfers between levels. The Company uses the carrying amounts of its restricted cash, prepaid expenses and other current assets, accounts payable and accrued expenses to approximate their fair value due to the short-term nature of these amounts.

Preferred Stock Tranche Rights

In October 2020, the Company issued Series A-1 convertible preferred stock ("Series A-1 Preferred Stock"). According to the Series A-1 Preferred Stock subscription agreement, the Company was obligated to issue second and third tranches of Series A-1 Preferred Stock upon the Company's successful completion of future science-driven milestone events, such as entering into in-licensing agreements, contracting with a CRO to conduct phase 2 clinical trials, and identifying compounds for lead drug candidates. As a result, the Company's obligation to issue additional Series A-1 Preferred Stock was recognized as a tranche obligation (the "Preferred Stock Tranche Rights"), which was subject to revaluation at each balance sheet date. Changes in fair value were recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss until the Preferred Stock Tranche Rights were settled (see Note 9).

The Company determined that the Preferred Stock Tranche Rights are freestanding financial instruments. The freestanding financial instruments were classified as a liability on the Company's consolidated balance sheets and initially recorded at fair value. The liability was subsequently remeasured to fair value at each reporting date until settled, and changes in the fair value of the preferred stock tranche liability were recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. The fair value of the Preferred Stock Tranche Rights was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. A change in the assumptions related to the valuation of the Preferred Stock Tranche Rights could have a significant impact on the value of the obligation.

The Preferred Stock Tranche Rights were valued as a forward contract. The value was determined using a probability-weighted present value calculation. In determining the fair value of the tranche rights obligation, estimates and assumptions impacting the fair value included the per share estimated fair value of the Company's Series A-1 Preferred Stock, discount rates, estimated time to tranche closing, and probability of each tranche closing. The Company determined the per share estimated fair value of the Series A-1 Preferred Stock by back-solving to the initial proceeds of the Series A-1 Preferred Stock financing. The Company remeasured the Preferred Stock Tranche Rights at each reporting period and prior to the settlement of the Preferred Stock Tranche Rights in January 2021.

The following reflects the ranges of significant quantitative inputs used in the valuation of the Preferred Stock Tranche Rights during the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Implied fair value of Series A-1 Preferred Stock	$2.35	$2.35
Discount rate	N/A	0.1%
Time to milestone event (years)	0.00	0.12 - 0.40
Probability of tranche closing	100%	70% - 90%

The following provides a roll forward of the fair value of the Preferred Stock Tranche Rights measured at fair value on a recurring basis using Level 3 significant unobservable inputs (in thousands):

Balance at December 31, 2019	$ —
Issuance of Preferred Stock Tranche Rights to purchase Series A-1 Preferred Stock	247
Change in fair value	71
Balance at December 31, 2020	318
Change in fair value	50
Fair value recognized as Series A-1 Preferred Stock upon settlement of Preferred Stock Tranche Rights	(368)
Balance at December 31, 2021	$ —

Convertible Notes

In 2018 and 2019, the Company entered into convertible notes purchase agreements (collectively, the "Notes") for a total aggregate borrowing amount of $4.8 million (see Note 8). The Notes contained various conversion features including mandatory conversion upon the occurrence of a qualified financing at a 20% or 50% discount. Upon the occurrence of a non-qualified financing, the holders of convertible notes issued in 2019 had the option to convert at the same terms as described above for a qualified financing. The Company elected the fair value option to account for the Notes. Changes in fair value were recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss until the Notes converted in October 2020.

The Notes were classified as a liability on the Company's consolidated balance sheets and initially recorded at fair value. The fair value of the Notes was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. A change in the assumptions related to the valuation of the Notes could have a significant impact on the value of the obligation.

The value of the Notes was determined using a probability-weighted present value calculation. In determining the fair value of the Notes, estimates and assumptions impacting the fair value primarily included the per share estimated fair value of the Company's Series A-1 Preferred Stock. The Company remeasured the Notes at each reporting period and prior to the conversion of the Notes in October 2020.

Immediately prior to conversion, the Notes were marked to fair value using the Series A-1 price of $2.28 per share. No gain or loss was recorded upon extinguishment.

The following provides a roll forward of the fair value of the Notes measured at fair value on a recurring basis using Level 3 significant unobservable inputs (in thousands):

Balance at December 31, 2019	$ 4,984
Change in fair value of convertible notes	2,099
Fair value recognized as Series A-1 Preferred Stock upon conversion of convertible notes	(7,083)
Balance at December 31, 2020	$ —

Anti-dilution Right

In accordance with a license agreement and stock issuance agreement between Eli Lilly and Company ("Lilly") and the Company (collectively, the "Lilly Agreement") entered into in January 2021, the Company was obligated to issue capital stock in a subsequent financing to Lilly in order to maintain a specified, single-digit percentage ownership of the Company upon specified conditions (the "Anti-dilution Right").

The Company determined that the Anti-dilution Right is a freestanding financial instrument. The freestanding financial instrument was classified as an asset or liability on the Company's consolidated balance sheets and initially recorded at fair value. The fair value of the Anti-dilution Right was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. A change in the assumptions related to the valuation of the Anti-dilution Right could have a significant impact on the value of the obligation.

The Anti-dilution Right was valued as a forward contract. The value was determined using a probability-weighted present value calculation. In determining the fair values of the obligation, estimates and assumptions impacting fair value included the per share estimated fair value of the Company's Series B convertible preferred stock ("Series B Preferred Stock"), discount rates, estimated time to share issuance and probability of each share issuance.

The Anti-dilution Right was subsequently revalued until anti-dilution shares were issued, with changes in fair value for each reporting period recognized in other income (expense), net in the consolidated statements of operations and comprehensive loss. Upon issuance of the anti-dilution shares, the fair value of the Anti-dilution Right was recognized as Series B Preferred Stock.

In accordance with the Anti-dilution Right, the Company issued Lilly 46,058 shares of Series B Preferred Stock in November 2021 in full satisfaction of the obligation.

The following reflects the ranges of significant quantitative inputs used in the valuation of the Anti-dilution Right during the year ended December 31, 2021:

	Year Ended December 31, 2021
Volatility	125%
Risk-free rate	0.0% - 0.1%
Discount rate	47.5%
Implied issuance price of Series B Preferred Stock	$0.84 - $6.11
Probability of settlement	10% - 100%

The following provides a roll forward of the fair value of the Anti-dilution Right measured at fair value on a recurring basis using Level 3 significant unobservable inputs (in thousands):

Balance at December 31, 2020	$ —
Issuance of Anti-dilution Right	233
Change in fair value of Anti-dilution Right	30
Fair value recognized as Series B Preferred Stock upon settlement of Anti-dilution Right	(263)
Balance at December 31, 2021	$ —

4. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Laboratory and computer equipment	$267	$ 78
Furniture	79	—
Total property and equipment	346	78
Less: accumulated depreciation	(56)	(19)
Property and equipment, net	$290	$ 59

Depreciation expense related to property and equipment for the years ended December 31, 2021 and 2020 was $37,000 and $13,000, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued compensation and benefits	$ 667	$334
Accrued research and development expenses	408	45
Accrued other	78	2
Accrued legal	67	38
Deferred sublease income	66	—
PPP loan payable	—	58
Total accrued expenses and other current liabilities	$1,286	$477

6. Leases

In April 2018, the Company entered into a lease agreement for laboratory and office space located at 700 N. Main Street, Cambridge, Massachusetts. The lease term, which commenced in April 2018 and was set to expire in April 2020, was extended in March 2020 for an additional one-year period. The lease was cancellable with 30 days' notice. The Company elected the short-term lease measurement and recognition exemption under ASC 842 for the one-year period extension and therefore did not recognize the lease on the Company's consolidated balance sheets.

In September 2020, the Company entered into an operating lease agreement, denominated in Swedish Krona, for office space located in Lund, Sweden. The term of the lease commenced in October 2020 and is scheduled to expire in September 2023, with lease payments being made on a quarterly basis.

In December 2020, the Company entered into a lease agreement for laboratory and office space located at 480 Arsenal Way, Watertown, Massachusetts (the "Arsenal Way Lease"). The term of the lease commenced in April 2021. The lease has an initial term from the rent commencement date, which is a month after the lease commencement date, of approximately seven years, with an option to extend the term for an additional five years at then-market rental rates. In connection with the execution of the lease agreement, the Company delivered a letter of credit of $0.3 million to the landlord, which is included in restricted cash in the accompanying consolidated balance sheets. The landlord contributed an aggregate of $0.7 million toward the cost of tenant improvements for the premises. Under the terms of the lease, the base rent is $1.0 million, subject to a 3% annual rent increase, plus an allocation of operating expenses and taxes.

In May 2021, the Company entered into an agreement to sublease 6,330 rentable square feet of its Arsenal Way Lease to a subtenant through March 2023. Sublease income is recognized on a straight-line basis over the term of the sublease agreement. Sublease rent income was $0.4 million for the year ended December 31, 2021, which was allocated and recorded as a reduction to general and administrative expenses and research and development expenses. The Company was not relieved of its primary obligation under the Arsenal Way Lease as a result of the sublease.

The Company recognizes monthly operating lease expense on a straight-line basis over the term of the lease as research and development or general and administrative expenses in the consolidated statement of operations and comprehensive loss. Variable lease expense relates primarily to office lease common area maintenance, insurance, and property taxes, is expensed as incurred, and is excluded from the calculation of the lease liabilities and right-of-use-assets. Variable lease expense for the year ended December 31, 2021 was $0.3 million.

The following table summarizes the presentation of the Company's operating leases on its consolidated balance sheet (in thousands):

Leases	Balance sheet classification	December 31, 2021
Assets:		
Operating lease assets	Operating lease right-of-use assets	$ 5,501
Total lease assets		$ 5,501
Liabilities:		
Current:		
Operating lease liabilities	Operating lease liability, current	$ 664
Noncurrent:		
Operating lease liabilities	Operating lease liability, long-term	4,964
Total lease liabilities		$ 5,628

The components of lease cost under ASC 842 included within research and development expenses and general and administrative expenses in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2021 were as follows (in thousands):

Lease cost	December 31, 2021
Operating lease cost	$ 1,144
Short-term lease cost	131
Variable lease cost	282
Sublease income	(291)
Total lease cost	$ 1,266

As of December 31, 2021, the weighted-average remaining lease term for operating leases was 6.3 years and the weighted-average discount rate was 7.85%. Cash paid for amounts included in the measurement of lease liabilities was $0.9 million for the year ended December 31, 2021.

Future minimum annual lease commitments under the Company's non-cancellable operating leases as of December 31, 2021 were as follows (in thousands):

Year ended December 31,	Amount
2022	$ 1,076
2023	1,087
2024	1,098
2025	1,131
2026	1,165
Thereafter	1,604
Total lease payments	7,161
Less: interest	(1,533)
Present value of operating lease liabilities	$ 5,628

Disclosures under ASC 840

The Company recognizes rent expense on a straight-line basis over the respective lease period. During the year ended December 31, 2020, rent expense was $0.4 million.

Future minimum rental commitments to be paid by the Company at December 31, 2020 is as follows (in thousands):

Year ending December 31,	Amount
2021	$ 175
2022	31
2023	31
2024	—
2025	—
	$ 237

Expected future lease payments of $7.7 million related to the Arsenal Way lease are not included in the table above. This lease agreement was signed in December 2020 and had not commenced as of December 31, 2020.

7. License Agreement

In January 2021, the Company entered into the Lilly Agreement with Lilly, pursuant to which the Company has been granted an exclusive, royalty-bearing sublicensable license to certain patents owned or controlled by Lilly, to commercially develop, manufacture, use, distribute and sell therapeutic products containing the compound prexasertib. The license from Lilly comprises three families of patent filings all relating to ACR-368. Additionally, pursuant to the Lilly Agreement, the Company received ACR-368 drug substance and drug product to be used in future research.

As initial consideration for the license, the Company made a one-time, non-creditable, non-refundable upfront payment of $5.0 million. As additional consideration for the license, the Company is required to pay Lilly aggregate development and commercial milestone payments of up to $168.0 million, of which $5.0 million is due prior to a new drug application.

The Company is also obligated to pay a tiered percentage royalty on annual net sales ranging from a low single-digit up to a maximum of 10%, subject to certain specified reductions. Royalties are payable by the Company on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last valid claim covering the licensed product in such country, expiration of all applicable regulatory exclusivities in such country for such licensed product and the tenth anniversary of the first commercial sale of such licensed product in such country, provided, that the Company's obligation to pay royalties for a given licensed product in a given country will expire earlier upon achievement of certain sales thresholds by generic products in such country.

In addition to the cash consideration described above, the Company issued 336,575 shares of its common stock to Lilly in an amount equal to 5.0% of the Company's capital stock on a fully diluted basis as of the date of the Lilly Agreement. The Company agreed to issue its capital stock to Lilly pursuant to the Anti-dilution Right (see Note 3).

In November 2021, the Company completed its Series B Preferred Stock financing. The financing triggered the settlement of the Anti-dilution Right, resulting in the issuance of 46,058 shares of Series B Preferred Stock to Lilly with a then fair value of $0.3 million.

The Company determined that the Lilly Agreement represented an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in the group of IPR&D assets, which all were similarly identifiable assets, with no alternative future use and recognized the aggregate acquisition cost as acquired IPR&D expense in the consolidated statements of operations and comprehensive loss. For the year ended December 31, 2021, the Company recognized $5.5 million of research and development expense in

connection with the consideration due under the Lilly Agreement. The $5.5 million consisted of (i) $0.2 million initial recognition of the Anti-dilution Right, (ii) $0.3 million fair value for the 336,575 shares of common stock issued to Lilly and (iii) the upfront cash consideration for the license arrangement of $5.0 million. To date, no milestones have been achieved and no royalties have been incurred related to the Lilly Agreement.

8. Debt

PPP Loan

In April 2020, the Company issued a promissory note to Silicon Valley Bank, pursuant to which it received loan proceeds of $0.1 million (the "PPP Loan") provided under the Paycheck Protection Program ("PPP"), which was established under the Coronavirus Aid, Relief and Economic Security Act and guaranteed by the Small Business Administration ("SBA"). The PPP loan was recorded within accrued expenses and other current liabilities on the Company's consolidated balance sheets. In February 2021, the Company received notice from the SBA that the PPP Loan was forgiven. Accordingly, the Company was no longer required to repay the $0.1 million in principal and immaterial accrued interest borrowed under the PPP Loan. A gain on extinguishment of the PPP Loan of $0.1 million was recorded as other income (expense), net for the year ended December 31, 2021.

Convertible Notes

In April 2018, the Company commenced an offering to issue $1.8 million of convertible notes (the "2018 Notes") to certain investors with a maturity date in April 2020. The 2018 Notes carried an interest rate of 4.0% per annum. The 2018 Notes carried both a voluntary conversion feature and an automatic conversion feature. Under the terms of the 2018 Notes, the 2018 Notes were automatically converted into shares of Series A-1 Preferred Stock at price per share equal to between 50% and 80% of the Series A-1 Preferred Stock price of $2.28 per share.

In June 2019, the Company commenced an offering to issue up to $3.0 million of convertible notes (the "2019 Notes") to certain investors with a maturity date in June 2020, which was subsequently extended to December 31, 2020. In June 2019, the Company issued an initial $1.5 million of convertible notes. Subsequently, the Company issued an additional $1.5 million of convertible notes in December 2019. The 2019 Notes were secured by specific assets of the Company and carried an interest rate of 8.0% per annum. The 2019 Notes carried both a voluntary conversion feature and an automatic conversion feature. Under the terms of the 2019 Notes, the 2019 Notes were optionally converted into shares of Series A-1 Preferred Stock at price per share equal to 80% of the Series A-1 Preferred Stock price of $2.28 per share.

The Company elected the fair value option to account for the Notes, whereby the Company recognized the Notes as liabilities at fair value, with subsequent changes in the fair value recognized in other income (expense), net on the consolidated statements of operations and comprehensive loss. At issuance, the fair value of the 2019 Notes and 2018 Notes was determined to be $1.8 million and $3.0 million, respectively. The Company incurred an immaterial amount of fees related to the issuance of the Notes, which was expensed to general and administrative expense on the consolidated statements of operations and comprehensive loss.

In October 2020, the Company entered into the Series A-1 Preferred Stock purchase agreement (the "Series A-1 Agreement"). As part of the Series A-1 Preferred Stock issuance, the Company settled the outstanding principal of the 2018 Notes and 2019 Notes of $4.8 million plus accrued interest of $0.4 million through the issuance of 3,106,561 shares of Series A-1 Preferred Stock.

The Company had no debt outstanding as of December 31, 2021.

9. Convertible Preferred Stock

Series A-1 Preferred Stock

In October 2020, the Board of Directors (the "Board") authorized the sale and issuance of Series A-1 Preferred Stock in three closings. In October 2020, as part of the first closing of the Series A-1 Preferred Stock, the Company issued 1,315,789 shares of Series A-1 Preferred Stock with a par value of $0.001 and a purchase price of $2.28 per share, and an additional 3,106,561 shares of the Series A-1 Preferred Stock upon conversion of the Company's convertible notes (see Note 8). The second and third closings of the Series A-1 Preferred Stock financing were dependent upon the Company's successful completion of future science-driven milestone events, such as entering into in-licensing agreements, contracting with a CRO to conduct phase 2 clinical trials, and identifying compounds for lead drug candidates. The obligations to issue additional shares of Series A-1 Preferred Stock in subsequent financings, or Preferred Stock Tranche Rights, were recorded as a liability (see Note 3).

In January 2021, upon effectiveness of the Lilly Agreement, the Company completed the second and third closings and issued an aggregate of 5,482,456 shares of Series A-1 Preferred Stock. Series A-1 Preferred Stock issued in the second and third closings had a par value of $0.001 and had a purchase price of $2.28 per share, which was equal to fair value as estimated by the Company's management by taking into consideration the results obtained from a third-party valuation, among other factors.

The Company incurred issuance costs of $0.2 million in connection with these transactions.

Series B Preferred Stock

In November 2021, the Board authorized the sale and issuance of Series B Preferred Stock. In November 2021, the Company issued 17,521,047 shares of Series B Preferred Stock, with a par value of $0.001 and a purchase price of $5.70742 per share, and an additional 46,058 shares of Series B Preferred Stock to settle the Company's Anti-dilution Right in connection with the Lilly Agreement (see Note 3). The Company incurred issuance costs of $0.2 million in connection with this transaction.

Upon the issuance of Series A-1 Preferred Stock and Series B Preferred Stock (collectively, "Preferred Stock"), the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features.

Preferred Stock consisted of the following as of the dates presented (in thousands, except share amounts):

	December 31, 2021				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	9,904,806	9,904,806	$ 22,502	$ 22,583	4,016,545
Series B Preferred Stock	17,567,105	17,567,105	100,016	100,263	7,123,717
Total	27,471,911	27,471,911	$ 122,518	$ 122,846	11,140,262

	December 31, 2020				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	9,685,508	4,422,350	$ 9,667	$ 10,083	1,793,328
Total	9,685,508	4,422,350	$ 9,667	$ 10,083	1,793,328

The holders of Preferred Stock have the following rights, preferences and privileges:

Voting

The holder of each share of Preferred Stock is entitled to one vote for each share of common stock into which it would convert and to vote with the common stock on all matters.

Conversion

Each share of Preferred Stock is convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the original issue price by the conversion price for each series of Preferred Stock (as defined below). The conversion price, and the rate at which each series of preferred stock may be converted into common stock, are subject to adjustment from time to time to reflect future share dividends, splits, combinations, recapitalizations and similar events.

Further, each share of Preferred Stock shall automatically be converted into shares of common stock at the conversion rate at the time in effect for such series of Preferred Stock immediately upon either of: (i) the closing of the Company's sale of common stock to the public at a price per share of at least $28.1489 per share in an IPO (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the applicable class of common stock), resulting in at least $50.0 million of proceeds, net of the underwriting discount and commissions; or (ii) the date and time, or occurrence of an event, specified by vote or written consent of the requisite holders of at a majority of the combined voting power of the shares of Preferred Stock then outstanding as calculated on an as-converted to common stock basis.

Dividends

The holders of the Preferred Stock are entitled to receive dividends at the rate of 6% of the applicable original issue price per annum, as potentially adjusted for certain non-dilutive transactions. Dividends shall not be cumulative or compounded and shall be payable only when, as and if declared by the Board and in preference and in priority to any dividends on common stock. There have been no dividends declared by the Board as of December 31, 2021.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company ("Liquidation Event"), the holders of Preferred Stock (first to the holders of Series B Preferred Stock, then to the holders of Series A-1 Preferred Stock) are entitled to receive prior and in preference to the holders of common stock, an amount equal to an amount per share equal to the greater of the original issue price, as potentially adjusted for certain non-dilutive transactions, plus all declared and unpaid dividends on the Preferred Stock or the price per share that would be received if the Preferred Stock were converted to common stock. If the assets and funds available to be distributed to all holders of Preferred Stock are insufficient to permit the payment, in full, of any of the liquidation preferences, then the entire assets and funds legally available for distribution to holders of the Preferred Stock shall be distributed ratably among the holders of Preferred Stock, acting as a single class, at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

After the payment of the full liquidation preference of the Preferred Stock as set forth above, the remaining assets of the Company legally available for distribution in such Liquidation Event shall be distributed ratably to the holders of shares of common stock.

Redemption

The Preferred Stock does not have redemption rights, except for the contingent redemption upon the occurrence of a Liquidation Event.

10. Common Stock

As of December 31, 2021 and 2020, the Company's Amended and Restated Certificate of Incorporation authorized the Company to issue 40,013,683 and 20,000,000 shares of common stock, respectively, with a par value of $0.001.

The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock as set forth above.

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there are not any cumulative voting rights. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of shares of capital stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of preferred stock that may be required by terms of the Certificate of Incorporation.

As of December 31, 2021, and 2020, the Company has reserved the following shares of common stock for the potential conversion of outstanding preferred stock and exercise of stock options:

	December 31,	
	2021	2020
Preferred Stock, as converted	11,140,262	1,793,328
Options to purchase common stock	881,611	46,633
Remaining shares reserved for future issuance	2,194,906	899,266
Total	14,216,779	2,739,227

11. Stock-Based Compensation

2019 Stock Incentive Plan

The Company adopted the 2019 Stock Incentive Plan (the "2019 Plan") in June 2019 pursuant to which the Company can issue incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. Recipients of stock options or stock appreciation rights shall be eligible to purchase shares of the Company's common stock at an exercise price equal to the estimated fair market value of such stock on the date of grant. The exercise price may be less than fair market value if the stock award is granted pursuant to an assumption or substitution for another stock award in the event of a merger or sale of the Company. The maximum term of options granted under the 2019 Plan is ten years, and stock options typically vest over a four-year period. The Board may assign vesting terms to the stock option grants as deemed appropriate. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. At the discretion of the Board, unvested shares held by employees may accelerate vesting in the event of a change of control of the Company unless assumed or substituted by the acquirer or surviving entity. The 2019 Plan provided for the issuance of up to 422,749 shares of common stock, which was subsequently amended in November 2021 to allow for the issuance of up to 3,077,023 shares of common stock as of December 31, 2021, of which 2,194,906 shares of common stock remain available for future grant under the 2019 Plan.

Shares of unused common stock that cover awards that are expired, terminated, surrendered or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

Stock Options

The Company has granted stock options with service-based vesting conditions. Stock options typically vest over four years and have a maximum term of ten years. The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant.

The assumptions that the Company used in the Black-Scholes option-pricing model to determine the grant date fair value of stock options granted were as follows. No options were granted in the year ended December 31, 2020.

	December 31, 2021
Risk-free interest rate range	0.49% - 1.33%
Dividend yield	0.00%
Expected life of options (years)	5.0 - 6.2
Volatility rate range	70.77% - 79.18%
Fair value of common stock range	$1.04 - $3.88

The following table summarizes the Company's stock option activity under the 2019 Plan:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	46,633	$ 0.37	8.44	$ 31
Granted	859,712	1.65		
Exercised	(506)	1.04		
Forfeited or canceled	(24,228)	1.04		
Outstanding as of December 31, 2021	881,611	$ 1.60	9.18	$ 2,008
Vested and expected to vest as of December 31, 2021	881,611	$ 1.60	9.18	$ 2,008
Vested and exercisable as of December 31, 2021	433,184	$ 1.80	9.20	$ 898

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the end of the reporting period. There was no aggregate intrinsic value of options exercised during the years ended December 31, 2021 and 2020.

The weighted-average grant date fair value of the Company's stock options granted during the year ended December 31, 2021 was $1.04 per option. As of December 31, 2021, there was $0.4 million of unrecognized stock-based compensation expense related to the share-based compensation arrangements under the 2019 Plan. The Company expects to recognize this amount over a weighted-average period of 2.6 years.

The total fair value of options vested during the years ended December 31, 2021 and 2020, was $0.5 million and an insignificant amount, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss is as follows (in thousands):

	December 31,	
	2021	2020
Research and development	$411	$ 3
General and administrative	86	—
Total stock-based compensation expense	$497	$ 3

12. Income Taxes

For the years ended December 31, 2021 and 2020, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period, due to its uncertainty of realizing a benefit from those items. The Company's operating losses since inception have been generated in the United States and Sweden.

Loss before provision for income taxes consisted of the following (in thousands):

	December 31,	
	2021	2020
Deferred Tax Assets		
Net operating loss carryforward	$ 3,697	$ 1,079
R&D credit carryovers	160	60
Capitalized licenses	1,399	—
Accruals and reserves	257	69
Lease liability	1,474	—
Other	110	—
	7,097	1,208
Valuation allowance	(5,588)	(1,199)
Deferred tax asset	1,509	9
Deferred Tax Liabilities		
Fixed and intangible assets	(73)	(9)
Right-of-use asset	(1,436)	—
Deferred tax liability	(1,509)	(9)
Net deferred tax asset	$ —	$ —

The following reconciles the differences between income taxes computed at the federal statutory rate and the provision for income taxes:

	December 31,	
	2021	2020
Tax effected at statutory rate	21.0%	21.0%
State taxes	5.7	3.3
Other permanent adjustments	(0.1)	(0.8)
Convertible notes revaluation	0.0	(9.3)
Federal R&D credits	0.3	0.0
Change in valuation allowance	(26.9)	(14.2)
Total	—%	—%

The Company has had no income tax expense due to operating losses incurred since inception. The Company has evaluated the positive and negative evidence bearing upon the reliability of its deferred tax assets. Based on this, the Company has provided a valuation allowance for the full amount of the net deferred tax assets as the realization of the deferred tax assets is not determined to be more likely than not. During the years ended December 31, 2021 and 2020, the valuation allowance increased by $4.4 million and $0.7 million, respectively, primarily due to the increase in the Company's net operating loss carryovers ("NOLs") during the period. The changes in the valuation allowance were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Valuation allowance at beginning of the year	$ 1,199	$ 480
Increases (decreases) recorded to income tax provision	4,389	719
Valuation allowance at end of year	$ 5,588	$ 1,199

As of December 31, 2021, the Company had $13.9 million and $12.3 million of federal and state operating loss carryforwards, respectively. The federal NOLs are not subject to expiration and the state NOLs begin to expire in 2038. These loss carryforwards are available to reduce future federal taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The amount of loss carryforwards that may be utilized in any future period may be limited based upon changes in the ownership of the company's ultimate parent. The Company has not conducted a Section 382 study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study.

On December 18, 2015, the Protecting Americans from Tax Hikes ("PATH") Act of 2015 was signed into law. The PATH Act has created several R&D credit provisions, including allowing qualified small business to utilize the research credit against the employer portion of payroll tax (i.e., FICA tax) not exceeding $250,000 per year. This provision is available for credits generated in tax years beginning after 2015. The company qualifies as small business for 2021, and will elect to make a small business election.

The Company follows the provisions of ASC 740-10, "Accounting for Uncertainty in Income Taxes," which specifies how tax benefits for uncertain tax positions are to be recognized, measured, and recorded in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim period guidance, among other provisions. As of December 31, 2021 and 2020, the Company has not recorded any amounts for uncertain tax positions. As of December 31, 2021 and 2020, the Company had no reserves for uncertain tax positions. For the years ended December 31, 2021 and 2020, no estimated interest or penalties were recognized on uncertain tax positions.

The Company's tax returns for the years ended December 31, 2018 to December 31, 2021 remain open and subject to examination by the Internal Revenue Service, state, and applicable foreign taxing authorities.

13. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	December 31,	
	2021	2020
Numerator:		
Net loss attributable to common stockholders - basic and diluted	$ (16,243)	$ (5,306)
Denominator:		
Weighted-average number of common shares used in net loss per share - basic and diluted	1,743,382	1,432,480
Net loss per share - basic and diluted	$ (9.32)	(3.70)

The Company's potentially dilutive securities, which include Preferred Stock and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of December 31, 2021 and 2020 because including them would have had an anti-dilutive effect:

	December 31,	
	2021	2020
Preferred Stock	27,471,911	4,422,350
Options to purchase common stock	881,611	46,633

14. Commitments and Contingencies

Leases

The Company's commitments under its operating leases are described in Note 6.

License Agreements

The Company entered into a license agreement under which it is obligated to make fixed and contingent payments (see Note 7).

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or services as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its financial statements as of December 31, 2021 and 2020.

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of December 31, 2021 and 2020, there were no matters which would have a material impact on the Company's financial results.

Other Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing and other services. These contracts generally provide for termination upon notice and are cancelable without significant penalty or payment, and do not contain any minimum purchase commitments.

15. Employee Benefit Plans

Effective January 1, 2019, the Company adopted a 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. Since inception of the 401(k) Plan and through the year ended December 31, 2021 the Company has not made any contributions to the 401(k) Plan.

16. Related Party Transactions

The chief executive officer of the Company received a payment of $0.2 million from the Company during the year ended December 31, 2020, which was recorded as a general and administrative expense. The payment was in accordance with a founder patent license agreement, executed in April 2018, that granted an exclusive, worldwide, irrevocable, perpetual, royalty-free license under certain licensed patents for any and all purposes and uses, including without limitation and rights to sublicense through multiple tiers, for the reimbursement of agreed, estimated unreimbursed expenses incurred by the chief executive officer prior to the effective date of such agreement with respect to the preparation, filing, prosecution, protection and maintenance of certain licensed patents.

17. Subsequent Events

For its annual consolidated financial statements as of December 31, 2021 and for the year then ended, the Company evaluated subsequent events through August 12, 2022, the date on which those financial statements were issued, and, with respect to the reverse stock split described below, through November 3, 2022.

Option Grants

In March 2022, the Company granted options for the purchase of an aggregate of 710,709 shares of common stock, at an exercise price of $3.88 per share. The aggregate grant-date fair value of the options granted is $1.8 million, which is expected to be recognized as stock-based compensation expense over a weighted-average period of 3.8 years.

In June 2022, the Company granted options for the purchase of an aggregate of 486,613 shares of common stock, at an exercise price of $3.63 per share. The aggregate grant-date fair value of the options granted is $1.3 million, which is expected to be recognized as stock-based compensation expense over a weighted-average period of 3.8 years.

In August 2022, the Company granted options for the purchase of an aggregate 166,259 shares of common stock, at an exercise price of $4.07 per share. The aggregate grant-date fair value of the options granted is $0.5 million, which is expected to be recognized as stock-based compensation expense over a weighted-average period of 4.0 years.

Companion Diagnostic Agreement

In June 2022, the Company entered into a Companion Diagnostic Agreement (the "Akoya Agreement") with Akoya Biosciences, Inc. ("Akoya"). Pursuant to the Akoya Agreement, Akoya has agreed to co-develop, validate, and commercialize the Company's proprietary ACR-368 OncoSignature test, the companion diagnostic that will be used to identify patients with cancer most likely to respond to ACR-368. Subject to the terms of the Akoya Agreement, the Company paid Akoya a one-time, non-refundable, non-creditable upfront payment in the amount of $0.6 million. The Company is obligated to pay Akoya up to an aggregate of $10.3 million upon the achievement of specified development milestones. To date, development milestones have been achieved under the Akoya Agreement, resulting in aggregate payments of $2.0 million by the Company to Akoya. In addition, the Company will reimburse Akoya for certain pass-through costs.

Reverse Stock Split

On November 1, 2022, the Company effected a 1-for-2.466 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 9). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

INDEX TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Unaudited Condensed Consolidated Financial Statements for the Six Months Ended June 30, 2022 and 2021:

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ACRIVON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(in thousands, except share and per share data)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 83,861	$ 99,603
Prepaid expenses and other current assets	3,301	805
Total current assets	87,162	100,408
Property and equipment, net	2,080	290
Operating lease right-of-use assets	5,142	5,501
Restricted cash	388	388
Deferred offering costs	224	—
Total assets	$ 94,996	$ 106,587
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,902	$ 964
Accrued expenses and other current liabilities	1,844	1,286
Operating lease liabilities, current	706	664
Total current liabilities	4,452	2,914
Operating lease liabilities, long-term	4,602	4,964
Total liabilities	9,054	7,878
Commitments and contingencies (Note 12)		
Series A-1 convertible preferred stock, par value $0.001; 9,904,806 shares authorized, issued and outstanding as of June 30, 2022 and December 31, 2021; liquidation preference of $22.6 million as of June 30, 2022.	22,502	22,502
Series B convertible preferred stock, par value $0.001; 17,567,105 shares authorized, issued and outstanding as of June 30, 2022 and December 31, 2021; liquidation preference of $100.3 million as of June 30, 2022.	100,016	100,016
Stockholders' deficit:		
Common stock, par value $0.001; 40,013,683 shares authorized as of June 30, 2022 and December 31, 2021; 1,769,561 shares issued and outstanding as of June 30, 2022 and December 31, 2021.	2	2
Additional paid-in capital	1,327	1,054
Accumulated deficit	(37,905)	(24,865)
Total stockholders' deficit	(36,576)	(23,809)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 94,996	$ 106,587

The accompanying notes are an integral part of these condensed consolidated financial statements.

ACRIVON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(in thousands, except share and per share data)

	Six Months Ended June 30,	
	2022	2021
Operating expenses:		
Research and development	$ 10,145	$ 8,448
General and administrative	2,992	795
Total operating expenses	13,137	9,243
Loss from operations	(13,137)	(9,243)
Other income (expense):		
Other income, net	97	41
Change in fair value of preferred stock tranche rights	—	(50)
Change in fair value of anti-dilution right	—	(208)
Total other income (expense), net	97	(217)
Net loss and comprehensive loss	$ (13,040)	$ (9,460)
Net loss per share—basic and diluted	$ (7.37)	$ (5.50)
Weighted-average common stock outstanding—basic and diluted	1,769,561	1,718,569

The accompanying notes are an integral part of these condensed consolidated financial statements.

ACRIVON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(UNAUDITED)
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	27,471,911	$122,518	1,769,561	$ 2	$ 1,054	$ (24,865)	$ (23,809)
Stock-based compensation expense	—	—	—	—	273	—	273
Net loss	—	—	—	—	—	(13,040)	(13,040)
Balance at June 30, 2022	27,471,911	$122,518	1,769,561	$ 2	$ 1,327	$ (37,905)	$ (36,576)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	4,422,350	$ 9,667	1,432,480	$ 1	$ 208	$ (8,622)	$ (8,413)
Issuance of common stock related to license agreement with Eli Lilly	—	—	336,575	1	348	—	349
Issuance of Series A-1 convertible preferred stock, net of issuance costs of $33	5,321,132	12,467	—	—	—	—	—
Issuance of Series A-1 convertible preferred stock related to settlement of preferred stock tranche rights	161,324	368	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	166	—	166
Net loss	—	—	—	—	—	(9,460)	(9,460)
Balance at June 30, 2021	9,904,806	$ 22,502	1,769,055	$ 2	$ 722	$ (18,082)	$ (17,358)

The accompanying notes are an integral part of these condensed consolidated financial statements.

ACRIVON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (13,040)	$ (9,460)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	123	15
Stock-based compensation expense	273	166
Non-cash lease expense	359	341
License agreement paid for with common stock	—	349
Anti-dilution right assumed with license agreement	—	233
Change in fair value of preferred stock tranche rights	—	50
Change in fair value of anti-dilution right	—	208
Gain upon extinguishment of PPP loan	—	(58)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,496)	(50)
Accounts payable	449	144
Accrued expenses and other liabilities	410	206
Operating lease liabilities	(320)	(185)
Net cash used in operating activities	(14,242)	(8,041)
Cash flows from investing activities:		
Purchases of property and equipment	(1,489)	(101)
Net cash used in investing activities	(1,489)	(101)
Cash flows from financing activities:		
Proceeds from issuance of Series A-1 preferred stock in second and third closings, net of issuance costs	—	12,467
Payments of deferred offering costs	(11)	—
Net cash (used in) provided by financing activities	(11)	12,467
Net (decrease) increase in cash, cash equivalents, and restricted cash	(15,742)	4,325
Cash, cash equivalents and restricted cash at beginning of period	99,991	1,990
Cash, cash equivalents and restricted cash at end of period	$ 84,249	$ 6,315
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of preferred stock tranche rights recognized as Series A-1 preferred stock upon issuance of milestone shares	$ —	$ 368
Purchases of property and equipment included in accounts payable	424	—
Supplemental cash flow information:		
Right-of-use assets obtained in exchange for operating lease liability	—	6,201
Deferred offering costs in accounts payable and accrued expenses	213	—
Reconciliation of cash, cash equivalents, and restricted cash:		
Cash and cash equivalents	$ 83,861	$ 5,908
Restricted cash	388	407
Total cash, cash equivalents, and restricted cash	$ 84,249	$ 6,315

The accompanying notes are an integral part of these condensed consolidated financial statements.

ACRIVON THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of the Business

Acrivon Therapeutics, Inc., (the "Company") is a clinical stage biopharmaceutical company developing oncology medicines that the Company matches to patients whose tumors are predicted to be sensitive to each specific medicine by utilizing its proteomics-based patient responder identification platform. The Company's pipeline includes the Phase 2 lead program, ACR-368, referred to as prexasertib, a targeted oncology asset, as well as preclinical stage pipeline programs targeting critical nodes in the DNA Damage Response and cell cycle regulation pathways, including WEE1, a protein kinase, and PKMYT1, a closely related protein serine/threonine kinase.

The Company was incorporated in March 2018 under the laws of the state of Delaware, and its principal offices are in Watertown, Massachusetts. Also in March 2018, the Company formed Acrivon AB, a wholly-owned subsidiary of the Company, established in Lund, Sweden. In December 2021, the Company formed Acrivon Securities Corporation, a wholly-owned subsidiary, established in Massachusetts.

Liquidity

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying condensed consolidated financial statements were issued.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering drug candidates, research and development activities for ACR-368 and other compounds, establishing arrangements with third parties for the manufacture of its drug candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future.

Since its inception, the Company has funded its operations primarily with proceeds from the sales of shares of its convertible preferred stock and the issuance of convertible notes. The Company has incurred recurring losses since its inception, including net losses of $13.0 million and $9.5 million for the six months ended June 30, 2022, and 2021, respectively. As of June 30, 2022, the Company had an accumulated deficit of $37.9 million. To date, the Company has not generated any revenues and expects to continue generating operating losses for the foreseeable future as it continues to expand its research and development efforts.

The Company expects that its existing cash and cash equivalents of $83.9 million as of June 30, 2022 will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the date these condensed consolidated financial statements were issued.

The Company will need additional funding to support its planned operating activities. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all. If the Company is unable to obtain sufficient funding, it could be required to delay its development efforts, limit activities and reduce research and development costs, which could adversely affect its business prospects.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. Immediately prior to the closing of a qualifying public offering on specified terms, the Company's outstanding convertible preferred stock will convert into common stock (see Note 8).

In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, government or private-party grants, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or rights of the Company's stockholders.

If the Company is unable to obtain sufficient capital, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

COVID-19 Considerations

In March 2020, the World Health Organization declared the outbreak of the novel coronavirus, COVID-19, a pandemic. The pandemic has resulted in the closing of borders, enhanced health screenings, health care service preparation and delivery, quarantines, cancellations, disruptions to supply chains, as well as general concern and uncertainty. The Company cannot predict the future progression or full impact of the outbreak and its effects on the Company's business and operations. Additionally, COVID-19 has resulted in substantial market volatility and may result in a significant economic downturn. The Company will continue to actively monitor the current international and domestic impacts of and responses to COVID-19 and its related risks. The Company considered the potential effects of the COVID-19 pandemic on its financial statements and noted that there is no material effect on the condensed consolidated financial statements as of June 30, 2022 and 2021.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements for the years ended December 31, 2021 and 2020, included elsewhere in this prospectus. There have been no changes to the Company's significant accounting policies, except as noted below.

Basis of Presentation and Consolidation

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

The condensed consolidated 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 presentation of the Company's financial position at June 30, 2022 and the results of its operations and its cash flows for the six months ended June 30, 2022 and 2021. The condensed balance sheet as of December 31, 2021 was derived from audited annual financial statements but does not include all disclosures required by U.S. GAAP.

The results for the six months ended June 30, 2022 are not necessarily indicative of results to be expected for the full year or for any other subsequent interim period.

Recently Adopted Accounting Pronouncements

ASU 2019-12, Simplifying the Accounting for Income Tax

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Tax* ("ASU 2019-12"). The standard contains several provisions that reduce financial statement complexity including removing the exception to the incremental approach for intra-period tax expense allocation when a company has a loss from continuing operations and income from other items not included in continuing operations. The Company adopted this accounting standard as of January 1, 2022, with no material impact on its condensed consolidated financial statements.

3. Fair Value Measurement

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

		Fair Value Measurements at June 30, 2022 Using:		
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 79,104	$ 79,104	$ —	$ —
Total assets	$ 79,104	$ 79,104	$ —	$ —

		Fair Value Measurements at December 31, 2021 Using:		
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 79,000	$ 79,000	$ —	$ —
Total assets	$ 79,000	$ 79,000	$ —	$ —

As of June 30, 2022 and December 31, 2021, the Company's cash equivalents consisted of money market funds, classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment.

During the six months ended June 30, 2022 and year ended December 31, 2021, there were no transfers between levels. The Company uses the carrying amounts of its restricted cash, prepaid expenses and other current assets, accounts payable and accrued expenses to approximate their fair value due to the short-term nature of these amounts.

Preferred Stock Tranche Rights

In October 2020, the Company issued Series A-1 convertible preferred stock ("Series A-1 Preferred Stock"). According to the Series A-1 Preferred Stock subscription agreement, the Company was obligated to issue second and third tranches of Series A-1 Preferred Stock upon the Company's successful completion of future science-driven milestone events, such as entering into in-licensing agreements, contracting with a CRO to conduct phase 2 clinical trials, and identifying compounds for lead drug candidates. As a result, the Company's obligation to issue additional Series A-1 Preferred Stock was recognized as a tranche obligation (the "Preferred Stock Tranche Rights"), which was subject to revaluation at each balance sheet date. Changes in fair value were recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss until the Preferred Stock Tranche Rights were settled.

The Company determined that the Preferred Stock Tranche Rights are freestanding financial instruments. The freestanding financial instruments were classified as a liability on the Company's consolidated balance sheets and initially recorded at fair value. The liability was subsequently remeasured to fair value at each reporting date until settled in January 2021, and changes in the fair value of the preferred stock tranche liability were recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. The fair value of the Preferred Stock Tranche Rights was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The Preferred Stock Tranche Rights were valued as a forward contract. The value was determined using a probability-weighted present value calculation. In determining the fair value of the tranche rights obligation, estimates and assumptions impacting the fair value included the per share estimated fair value of the Company's Series A-1 Preferred Stock, discount rates, estimated time to tranche closing, and probability of each tranche closing. The Company determined the per share estimated fair value of the Series A-1 Preferred Stock by back-solving to the initial proceeds of the Series A-1 Preferred Stock financing. The Company remeasured the Preferred Stock Tranche Rights at each reporting period and prior to the settlement of the Preferred Stock Tranche Rights in January 2021.

The following reflects the ranges of significant quantitative inputs used in the valuation of the Preferred Stock Tranche Rights during the six months ended June 30, 2021, which reflects the inputs used at remeasurement prior to settlement in January 2021:

	Six Months Ended June 30, 2021
Implied fair value of Series A-1 Preferred Stock	$ 2.35
Discount rate	N/A
Time to milestone event (years)	0.00
Probability of tranche closing	100%

The following provides a roll forward of the fair value of the Preferred Stock Tranche Rights measured at fair value on a recurring basis using Level 3 significant unobservable inputs (in thousands):

Balance at December 31, 2020	$ 318
Change in fair value	50
Fair value recognized as Series A-1 Preferred Stock upon settlement of Preferred Stock Tranche Rights	(368)
Balance at June 30, 2021	$ —

Anti-dilution Right

In accordance with a license agreement and stock issuance agreement between Eli Lilly and Company ("Lilly") and the Company (collectively, the "Lilly Agreement") entered into in January 2021, the Company was obligated to issue capital stock in a subsequent financing to Lilly in order to maintain a specified, single-digit percentage ownership of the Company upon specified conditions (the "Anti-dilution Right").

The Company determined that the Anti-dilution Right is a freestanding financial instrument. The freestanding financial instrument was classified as an asset or liability on the Company's consolidated balance sheets and initially recorded at fair value. The fair value of the Anti-dilution Right was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. A change in the assumptions related to the valuation of the Anti-dilution Right could have a significant impact on the value of the obligation.

The Anti-dilution Right was valued as a forward contract. The value was determined using a probability-weighted present value calculation. In determining the fair values of the obligation, estimates and assumptions impacting fair value included the per share estimated fair value of the Company's Series B convertible preferred stock ("Series B Preferred Stock"), discount rates, estimated time to share issuance and probability of each share issuance.

The Anti-dilution Right was subsequently revalued until anti-dilution shares were issued in November 2021, with changes in fair value for each reporting period recognized in other income (expense), net in the consolidated statements of operations and comprehensive loss. Upon issuance of the anti-dilution shares, the fair value of the Anti-dilution Right was recognized as Series B Preferred Stock.

In full satisfaction of the Anti-dilution Right, the Company issued Lilly 46,058 shares of Series B Preferred Stock in November 2021.

The following reflects the ranges of significant quantitative inputs used in the valuation of the Anti-dilution Right during the six months ended June 30, 2021:

	Six Months Ended June 30, 2021
Volatility	125%
Risk-free rate	0.0% - 0.1%
Discount rate	47.5%
Implied issuance price of Series B	$ 0.84 - $6.11
Probability of settlement	10% - 40%

The following provides a roll forward of the fair value of the Anti-dilution Right measured at fair value on a recurring basis using Level 3 significant unobservable inputs (in thousands):

Balance at December 31, 2020	$ —
Issuance of Anti-dilution Right	233
Change in fair value of Anti-dilution Right	208
Balance at June 30, 2021	$441

4. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Laboratory and computer equipment	$2,087	$ 267
Furniture	172	79
Total property and equipment	2,259	346
Less: accumulated depreciation	(179)	(56)
Property and equipment, net	$2,080	$ 290

Depreciation expense related to property and equipment for the six months ended June 30, 2022 and 2021 was $0.1 million and $15,000, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Accrued compensation and benefits	$ 881	$ 667
Accrued research and development expenses	648	408
Accrued other	126	78
Accrued legal	189	67
Deferred sublease income	—	66
Total accrued expenses and other current liabilities	$ 1,844	$ 1,286

6. Leases

In April 2018, the Company entered into a lease agreement for laboratory and office space located at 700 N. Main Street, Cambridge, Massachusetts. The lease term, which commenced in April 2018 and was set to expire in April 2020, was extended in March 2020 for an additional one-year period. The lease was cancellable with 30 days' notice. The Company elected the short-term lease measurement and recognition exemption under ASC 842 for the one-year period extension and therefore did not recognize the lease on the Company's condensed consolidated balance sheets.

In September 2020, the Company entered into an operating lease agreement, denominated in Swedish Krona, for office space located in Lund, Sweden. The term of the lease commenced in October 2020 and is scheduled to expire in September 2023, with lease payments being made on a quarterly basis.

In December 2020, the Company entered into a lease agreement for laboratory and office space located at 480 Arsenal Way, Watertown, Massachusetts (the "Arsenal Way Lease"). The term of the lease commenced in April 2021. The lease has an initial term from the rent commencement date, which is a month after the lease commencement date, of approximately seven years, with an option to extend the term for an additional five years at then-market rental rates. In connection with the execution of the lease agreement, the Company delivered a letter of credit of $0.3 million to the landlord, which is included in restricted cash in the accompanying condensed consolidated balance sheets. The landlord contributed an aggregate of $0.7 million toward the cost of tenant improvements for the premises. Under the terms of the lease, the base rent is $1.0 million, subject to a 3% annual rent increase, plus an allocation of operating expenses and taxes.

In May 2021, the Company entered into an agreement to sublease 6,330 rentable square feet of its Arsenal Way Lease to a subtenant through March 2023. Sublease income is recognized on a straight-line basis over the term of the sublease agreement. Sublease rent income was $0.4 million and an insignificant amount for the six months ended June 30, 2022 and 2021, respectively, which was allocated and recorded as a reduction to general and administrative expenses and research and development expenses. The Company was not relieved of its primary obligation under the Arsenal Way Lease as a result of the sublease.

The Company recognizes monthly operating lease expense on a straight-line basis over the term of the lease as research and development or general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss. Variable lease expense relates primarily to office lease common area maintenance, insurance, and property taxes, is expensed as incurred, and is excluded from the calculation of the lease liabilities and right-of-use-assets. Variable lease expense for the six months ended June 30, 2022 and 2021 was $0.3 million and $0.1 million, respectively.

The following table summarizes the presentation of the Company's operating leases on its condensed consolidated balance sheet (in thousands):

Leases	Balance sheet classification	June 30, 2022	December 31, 2021
Assets:			
Operating lease assets	Operating lease right-of-use assets	$ 5,142	$ 5,501
Total lease assets		$ 5,142	$ 5,501
Liabilities:			
Current:			
Operating lease liabilities	Operating lease liability, current	$ 706	$ 664
Noncurrent:			
Operating lease liabilities	Operating lease liability, long-term	4,602	4,964
Total lease liabilities		$ 5,308	$ 5,628

The components of lease cost under ASC 842 included within research and development expenses and general and administrative expenses in the Company's condensed consolidated statement of operations and comprehensive loss for the six months ended June 30, 2022 were as follows (in thousands):

	Six Months Ended June 30,	
Lease cost	2022	2021
Operating lease cost	$ 571	$ 463
Short-term lease cost	—	131
Variable lease cost	262	68
Sublease income	(269)	(22)
Total lease cost	$ 564	$ 640

As of June 30, 2022 and 2021, the weighted-average remaining lease term for operating leases was 5.8 years and 6.6 years, respectively, and the weighted-average discount rate was 7.85% and 7.79%, respectively. Cash paid for amounts included in the measurement of lease liabilities was $0.5 million and $0.3 million for the six months ended June 30, 2022 and 2021, respectively.

Future minimum annual lease commitments under the Company's non-cancellable operating leases as of June 30, 2022 were as follows (in thousands):

Year ended December 31,	Amount
2022 (remaining 6 months)	$ 543
2023	1,087
2024	1,098
2025	1,131
2026	1,165
Thereafter	1,604
Total lease payments	6,628
Less: interest	(1,320)
Present value of operating lease liabilities	$ 5,308

7. License Agreement

In January 2021, the Company entered into a license agreement and stock issuance agreement (collectively, the "Lilly Agreement") with Eli Lilly and Company ("Lilly"), pursuant to which the Company has been granted an exclusive, royalty-bearing sublicensable license to certain patents owned or controlled by Lilly, to commercially develop, manufacture, use, distribute and sell therapeutic products containing the compound prexasertib. The license from Lilly comprises three families of patent filings all relating to ACR-368. Additionally, pursuant to the Lilly Agreement, the Company received ACR-368 drug substance and drug product to be used in future research.

As initial consideration for the license, the Company made a one-time, non-creditable, non-refundable upfront payment of $5.0 million. As additional consideration for the license, the Company is required to pay Lilly aggregate development and commercial milestone payments of up to $168.0 million, of which $5.0 million is due prior to a new drug application.

The Company is also obligated to pay a tiered percentage royalty on annual net sales ranging from single-digit up to a maximum of 10%, subject to certain specified reductions. Royalties are payable by the Company on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last valid claim covering the licensed product in such country, expiration of all applicable regulatory exclusivities in such country for such licensed product and the tenth anniversary of the first commercial sale of such licensed product in such country, provided, that the Company's obligation to pay royalties for a given licensed product in a given country will expire earlier upon achievement of certain sales thresholds by generic products in such country.

In addition to the cash consideration described above, the Company issued 336,575 shares of its common stock to Lilly in an amount equal to 5.0% of the Company's capital stock on a fully diluted basis as of the date of the Lilly Agreement. The Company agreed to issue its capital stock to Lilly pursuant to the Anti-dilution Right.

In November 2021, the Company completed its Series B Preferred Stock financing. The financing triggered the settlement of the Anti-dilution Right, resulting in the issuance of 46,058 shares of Series B Preferred Stock to Lilly with a then fair value of $0.3 million.

The Company determined that the Lilly Agreement represented an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in the group of IPR&D assets, which all were similarly identifiable assets with no alternative future use and recognized the aggregate acquisition cost as acquired IPR&D expense in the condensed consolidated statements of operations and comprehensive loss. During the six months ended June 30, 2021, the Company recognized $5.5 million of research and development expense in connection with the consideration due under the Lilly Agreement. The $5.5 million consisted of (i) $0.2 million initial recognition of the Anti-dilution Right, (ii) $0.3 million fair value for the 336,575 shares of common stock issued to Lilly and (iii) the upfront cash consideration for the license arrangement of $5.0 million. To date, no milestones have been achieved and no royalties have been incurred related to the Lilly Agreement.

8. Convertible Preferred Stock

Series A-1 Preferred Stock

In October 2020, the Board of Directors (the "Board") authorized the sale and issuance of Series A-1 Preferred Stock in three closings. In October 2020, as part of the first closing of the Series A-1 Preferred Stock, the Company issued 1,315,789 shares of Series A-1 Preferred Stock with a par value of $0.001 and a purchase price of $2.28 per share, and an additional 3,106,561 shares of the Series A-1 Preferred Stock upon conversion of the Company's convertible notes. The second and third closings of the Series A-1 Preferred Stock financing were dependent upon the Company's successful completion of future science-driven milestone events, such as entering

into in-licensing agreements, contracting with a CRO to conduct phase 2 clinical trials, and identifying compounds for lead drug candidates. The obligations to issue additional shares of Series A-1 Preferred Stock in subsequent financings, or Preferred Stock Tranche Rights, were recorded as a liability.

In January 2021, upon effectiveness of the Lilly Agreement, the Company completed the second and third closings and issued an aggregate of 5,482,456 shares of Series A-1 Preferred Stock. Series A-1 Preferred Stock issued in the second and third closings had a par value of $0.001 and had a purchase price of $2.28 per share, which was equal to fair value as estimated by the Company's management by taking into consideration the results obtained from a third-party valuation, among other factors.

The Company incurred issuance costs of $0.2 million in connection with these transactions.

Series B Preferred Stock

In November 2021, the Board authorized the sale and issuance of Series B Preferred Stock. In November 2021, the Company issued 17,521,047 shares of Series B Preferred Stock, with a par value of $0.001 and a purchase price of $5.70742 per share, and an additional 46,058 shares of Series B Preferred Stock to settle the Company's Anti-dilution Right in connection with the Lilly Agreement. The Company incurred issuance costs of $0.2 million in connection with this transaction.

Upon the issuance of Series A-1 Preferred Stock and Series B Preferred Stock (collectively, "Preferred Stock"), the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features.

Preferred Stock consisted of the following as of June 30, 2022 and December 31, 2021 (in thousands, except share amounts):

	June 30, 2022				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	9,904,806	9,904,806	$ 22,502	$ 22,583	4,016,545
Series B Preferred Stock	17,567,105	17,567,105	100,016	100,263	7,123,717
Total	27,471,911	27,471,911	$ 122,518	$ 122,846	11,140,262

	December 31, 2021				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	9,904,806	9,904,806	$ 22,502	$ 22,583	4,016,545
Series B Preferred Stock	17,567,105	17,567,105	100,016	100,263	7,123,717
Total	27,471,911	27,471,911	$ 122,518	$ 122,846	11,140,262

The holders of Preferred Stock have the following rights, preferences and privileges:

Voting

The holder of each share of Preferred Stock is entitled to one vote for each share of common stock into which it would convert and to vote with the common stock on all matters.

Conversion

Each share of Preferred Stock is convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the original issue price by the conversion price for each series of Preferred Stock (as defined below). The conversion price, and the rate at which each series of preferred stock may be converted into common stock, are subject to adjustment from time to time to reflect future share dividends, splits, combinations, recapitalizations and similar events.

Further, each share of Preferred Stock shall automatically be converted into shares of common stock at the conversion rate at the time in effect for such series of Preferred Stock immediately upon either of: (i) the closing of the Company's sale of common stock to the public at a price per share of at least $28.1489 per share in an IPO (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the applicable class of common stock), resulting in at least $50.0 million of proceeds, net of the underwriting discount and commissions; or (ii) the date and time, or occurrence of an event, specified by vote or written consent of the requisite holders of at a majority of the combined voting power of the shares of Preferred Stock then outstanding as calculated on an as-converted to common stock basis.

Dividends

The holders of the Preferred Stock are entitled to receive dividends at the rate of 6% of the applicable original issue price per annum, as potentially adjusted for certain non-dilutive transactions. Dividends shall not be cumulative or compounded and shall be payable only when, as and if declared by the Board and in preference and in priority to any dividends on common stock. There have been no dividends declared by the Board as of June 30, 2022 and December 31, 2021.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company ("Liquidation Event"), the holders of Preferred Stock (first to the holders of Series B Preferred Stock, then to the holders of Series A-1 Preferred Stock) are entitled to receive prior and in preference to the holders of common stock, an amount equal to an amount per share equal to the greater of the original issue price, as potentially adjusted for certain non-dilutive transactions, plus all declared and unpaid dividends on the Preferred Stock or the price per share that would be received if the Preferred Stock were converted to common stock. If the assets and funds available to be distributed to all holders of Preferred Stock are insufficient to permit the payment, in full, of any of the liquidation preferences, then the entire assets and funds legally available for distribution to holders of the Preferred Stock shall be distributed ratably among the holders of Preferred Stock, acting as a single class, at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

After the payment of the full liquidation preference of the Preferred Stock as set forth above, the remaining assets of the Company legally available for distribution in such Liquidation Event shall be distributed ratably to the holders of shares of common stock.

Redemption

The Preferred Stock does not have redemption rights, except for the contingent redemption upon the occurrence of a Liquidation Event.

9. Common Stock

As of June 30, 2022 and December 31, 2021, the Company's Amended and Restated Certificate of Incorporation authorized the Company to issue 40,013,683 shares of common stock, respectively, with a par value of $0.001.

The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock as set forth above.

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there are not any cumulative voting rights. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of shares of capital stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of preferred stock that may be required by terms of the Certificate of Incorporation.

As of June 30, 2022 and December 31, 2021, the Company has reserved the following shares of common stock for the potential conversion of outstanding preferred stock and exercise of stock options:

	June 30, 2022	December 31, 2021
Preferred Stock, as converted	11,140,262	11,140,262
Options to purchase common stock	2,072,851	881,611
Remaining shares reserved for future issuance	1,003,666	2,194,906
Total	14,216,779	14,216,779

10. Stock-Based Compensation

2019 Stock Incentive Plan

The Company adopted the 2019 Stock Incentive Plan (the "2019 Plan") in June 2019 pursuant to which the Company can issue incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. Recipients of stock options or stock appreciation rights shall be eligible to purchase shares of the Company's common stock at an exercise price equal to the estimated fair market value of such stock on the date of grant. The exercise price may be less than fair market value if the stock award is granted pursuant to an assumption or substitution for another stock award in the event of a merger or sale of the Company. The maximum term of options granted under the 2019 Plan is ten years, and stock options typically vest over a four-year period. The Board may assign vesting terms to the stock option grants as deemed appropriate. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. At the discretion of the Board, unvested shares held by employees may accelerate vesting in the event of a change of control of the Company unless assumed or substituted by the acquirer or surviving entity. The 2019 Plan provided for the issuance of up to 422,749 shares of common stock, which was subsequently amended in November 2021 to allow for the issuance of up to 3,077,023 shares of common stock as of June 30, 2022, of which 1,003,666 shares of common stock remain available for future grant under the 2019 Plan.

Shares of unused common stock that cover awards that are expired, terminated, surrendered or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

Stock Options

The Company has granted stock options with service-based vesting conditions. Stock options typically vest over four years and have a maximum term of ten years. The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant.

The following table summarizes the Company's stock option activity under the 2019 Plan:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	881,611	$ 1.60	9.18	$ 2,008
Granted	1,197,322	3.78		
Exercised	—	—		
Forfeited or canceled	(6,082)	3.88		
Outstanding as of June 30, 2022	2,072,851	$ 2.85	9.36	$ 1,836
Vested and expected to vest as of June 30, 2022	2,072,851	$ 2.85	9.36	$ 1,836
Vested and exercisable as of June 30, 2022	608,125	$ 1.92	8.80	$ 1,091

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the end of the reporting period.

The weighted-average grant date fair value of the Company's stock options granted during the six months ended June 30, 2022 was $2.54 per option. As of June 30, 2022, there was $3.1 million of unrecognized stock-based compensation expense related to the share-based compensation arrangements under the 2019 Plan. The Company expects to recognize this amount over a weighted-average period of 3.3 years.

The total fair value of options vested during the six months ended June 30, 2022 and 2021, was $0.2 million and $0.1 million, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense included in the Company's condensed consolidated statements of operations and comprehensive loss is as follows (in thousands):

	Six Months Ended June 30,	
	2022	2021
Research and development	$ 178	$ 105
General and administrative	95	61
Total stock-based compensation expense	$ 273	$ 166

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Six Months Ended June 30,	
	2022	2021
Numerator:		
Net loss attributable to common stockholders—basic and diluted	$ (13,040)	$ (9,460)
Denominator:		
Weighted-average number of common shares used in net loss per share—basic and diluted	1,769,561	1,718,569
Net loss per share—basic and diluted	$ (7.37)	$ (5.50)

The Company's potentially dilutive securities, which include Preferred Stock and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of June 30, 2022 and 2021 because including them would have had an anti-dilutive effect:

	June 30,	
	2022	2021
Preferred Stock	27,471,911	9,904,806
Options to purchase common stock	2,072,851	705,751

12. Commitments and Contingencies

Leases

The Company's commitments under its operating leases are described in Note 6.

License Agreement

The Company entered into a license agreement under which it is obligated to make fixed and contingent payments (see Note 7).

Companion Diagnostic Agreement

In June 2022, the Company entered into a companion diagnostic agreement (the "Akoya Agreement") with Akoya Biosciences, Inc. ("Akoya"), pursuant to which the Company has engaged Akoya to co-develop, validate, and commercialize the Company's proprietary ACR-368 OncoSignature test, the companion diagnostic that will be used to identify patients with cancer most likely to respond to ACR-368. Subject to the terms of the Akoya Agreement, the Company paid Akoya a one-time, non-refundable, non-creditable upfront payment in the amount of $0.6 million. The Company is obligated to pay Akoya up to an aggregate of $10.3 million upon the achievement of specified development milestones. Through the issuance date of the unaudited condensed consolidated financial statements, milestones under the Akoya Agreement were achieved and the Company has made aggregate payments of $2.0 million to Akoya. Of the $2.0 million aggregate milestone payments, $1.6 million, which was recorded as research and development expense, was paid through June 30, 2022 and the remaining $0.4 million was paid in the third quarter of 2022 when an additional milestone was achieved.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or services as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its financial statements as of June 30, 2022 and December 31, 2021.

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of June 30, 2022 and 2021, there were no matters which would have a material impact on the Company's financial results.

Other Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing and other services. These contracts generally provide for termination upon notice and are cancelable without significant penalty or payment, and do not contain any minimum purchase commitments.

13. Employee Benefit Plans

Effective January 1, 2019, the Company adopted a 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. Since inception of the 401(k) Plan and through the six months ended June 30, 2022, the Company has not made any contributions to the 401(k) Plan.

14. Subsequent Events

For its condensed consolidated financial statements as of the six months ended June 30, 2022 and for the period then ended, the Company evaluated subsequent events through August 12, 2022, the date on which those financial statements were issued, and through November 8, 2022, the date of the filing of the Company's registration statement.

Option Grants

In August 2022, the Company granted options for the purchase of an aggregate 166,259 shares of common stock, at an exercise price of $4.07 per share. The aggregate grant-date fair value of the options granted is $0.5 million, which is expected to be recognized as stock-based compensation expense over a weighted-average period of 4.0 years.

Akoya Milestone Achievement

In September 2022, the Company achieved an additional development milestone under the Akoya Agreement and made a payment of $0.3 million to Akoya.

Amended and Restated Certificate of Incorporation

On October 25, 2022, the Board approved the amended and restated certificate of incorporation, which will be filed upon the closing of the IPO and which, among other things, increases the number of shares of common stock authorized for issuance from 40,013,683 to 500,000,000 shares of common stock.

2022 Equity Incentive Plan

On October 28, 2022, the Board adopted, and on November 1, 2022 its stockholders approved, the 2022 Stock Option and Incentive Plan (the "2022 Plan"), which will become effective on the date of the underwriting agreement related to this offering. The 2022 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors, and consultants. The 2022 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares initially reserved for issuance under the 2022 Plan is 5,606,723 shares, which is the sum of: (i) 2,555,271 new shares, plus (ii) the number of shares that remain available for issuance under the 2019 Plan at the time the 2022 Plan becomes effective and (iii) up to 2,148,679 shares of common stock subject to awards granted under the 2019 Plan that, after the effective date of the 2022 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased. In addition, the number of shares reserved and available for issuance under the 2022 Plan will automatically increase on January 1, 2023 and each January 1 thereafter, by five percent of the aggregate number of shares of common stock of all classes issued and outstanding on the immediately preceding December 31 or such lesser number of shares as determined by the compensation committee.

The shares of common stock underlying any awards under the 2022 Plan and the 2019 Plan that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company 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 2022 Plan.

2022 Employee Stock Purchase Plan

On October 28, 2022, the Board adopted, and on November 1, 2022 its stockholders approved, the 2022 Employee Stock Purchase Plan (the "2022 ESPP"), which will become effective on the date of the underwriting agreement related to this offering. A total of 215,000 shares of common stock were initially reserved for issuance under this plan. The number of shares of common stock that may be issued under the 2022 ESPP shall cumulatively increase beginning on January 1, 2023 and each January 1 thereafter through January 1, 2032, by one percent 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 compensation committee.

Reverse Stock Split

On November 1, 2022, the Company effected a 1-for-2.466 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 8). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

5,900,000 Shares

Common Stock

PROSPECTUS

MORGAN STANLEY *JEFFERIES* *COWEN* *PIPER SANDLER*

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq Global Market initial listing fee.

	Amount
SEC registration fee	$ 13,459
FINRA filing fee	18,820
Nasdaq listing fee	150,000
Accountants' fees and expenses	950,000
Legal fees and expenses	1,400,000
Transfer agent's fees and expenses	4,750
Printing and engraving expenses	250,000
Miscellaneous	112,971
Total expenses	$ 2,900,000

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the Delaware General Corporation Law, our amended and restated certificate of incorporation and bylaws to be in effect upon the closing of this offering will provide that: (i) we are required to indemnify our directors to the fullest extent permitted by the Delaware General Corporation Law; (ii) we may, in our discretion, indemnify our officers, employees and other agents as set forth in the Delaware General Corporation Law; (iii) we are required, upon satisfaction of certain conditions, to advance all expenses incurred

by our directors in connection with certain legal proceedings; (iv) the rights conferred in the bylaws are not exclusive; and (v) we are authorized to enter into indemnification agreements with our directors, officers, employees and agents.

In connection with this offering, we expect to enter into indemnification agreements with each of our directors and executive officers that require us to indemnify them against expenses, judgments, fines, settlements and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director or officer of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. The indemnification agreements will also set forth certain procedures that will apply in the event of a claim for indemnification thereunder. At present, no litigation or proceeding is pending that involves any of our directors or officers regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

In addition, the underwriting agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act, or otherwise. Our amended and restated investors' rights agreement with certain investors also provides for cross-indemnification in connection with the registration of our common stock on behalf of such investors.

Item 15. Recent Sales of Unregistered Securities

The following list sets forth information regarding all unregistered securities sold by us since our inception through the date of the prospectus that forms a part of this registration statement.

Issuances of Common Stock

In April 2018, we issued 871,857 shares of our common stock to one accredited investor as consideration for a license to certain patent rights.

In April 2018, we issued an aggregate of 334,549 shares of our common stock to one accredited investor and one unaccredited investor at a purchase price of $0.003 per share, for aggregate consideration of $825.00.

In July 2018, we issued 185,523 shares of our common stock to one sophisticated unaccredited investor at a purchase price of $0.003 per share, for aggregate consideration of $457.50.

In August 2018, we issued 278,284 shares of our common stock to one sophisticated unaccredited investor at a purchase price of $0.003 per share, for aggregate consideration of $686.25, of which 237,733 shares were repurchased in April 2019 in connection with the termination of such investor's consulting agreement.

In January 2021, we issued 336,575 shares of our common stock to one accredited investor as partial consideration for a license to certain patent rights.

Issuances of Preferred Stock

In October 2020, we issued (a) 1,315,789 shares of our Series A-1 convertible preferred stock to one investor at a purchase price of $2.28 per share, for aggregate consideration of $3.0 million, (b) 1,918,745 shares

of our Series A-1 convertible preferred stock to one investor upon conversion of outstanding convertible notes in aggregate principal amount of $2,750,000 at a conversion price of $3.87 per share, and (c) 1,187,816 shares of our Series A-1 convertible preferred stock to one investor upon conversion of outstanding convertible notes in aggregate principal amount of $2,000,000 at a conversion price of $4.50 per share.

In January 2021, we issued an aggregate of 5,482,456 shares of our Series A-1 convertible preferred stock to two investors at a purchase price of $2.28 per share, for aggregate consideration of $12.5 million.

In November 2021, we issued (a) an aggregate of 17,521,047 shares of our Series B convertible preferred stock to 13 investors at a purchase price of $5.70742 per share, for aggregate consideration of $100.0 million, and (b) 46,058 shares of our Series B convertible preferred stock to one accredited investor in satisfaction of a contractual obligation contained in a license to certain patent rights.

Issuances Pursuant to our Equity Plans

From March 13, 2018 (the date of our inception) through the date of this registration statement, we granted options under our 2019 Stock Incentive Plan to purchase an aggregate of 2,269,926 shares of common stock, at a weighted-average exercise price of $2.92 per share, to our employees, directors and consultants. Of these, 25,545 shares have been issued upon the exercise of options for aggregate consideration of $23,997.50 and options for the purchase of 95,702 shares of common stock have been forfeited, expired or canceled.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

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Item 16. ***Exhibits and Financial Statement Schedules.***

(a) Exhibits.

The exhibits listed below are filed as part of this registration.

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement
3.1*	Second Amended and Restated Certificate of Incorporation of the Registrant (as amended and currently in effect)
3.2*	Bylaws of the Registrant (currently in effect)
3.3*	Form of Amended and Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4*	Form of Amended and Restated Bylaws of the Registrant (to be effective upon the closing of this offering)
3.5*	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation
4.1*	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated November 9, 2021
5.1*	Opinion of Cooley LLP
10.1*	2019 Stock Incentive Plan and Forms of Stock Option Agreement and Notice of Exercise
10.2*	2022 Equity Incentive Plan and Forms of Stock Option Grant Notice, Stock Option Agreement, Notice of Exercise, Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement
10.3*	2022 Employee Stock Purchase Plan
10.4*	Form of Indemnification Agreement with Executive Officers and Directors
10.5†*	License Agreement, by and between the Registrant and Eli Lilly and Company, dated January 27, 2021
10.6†*	OncoSignature Companion Diagnostic Agreement, by and between the Registrant and Akoya Biosciences, Inc., dated June 17, 2022
10.7†#*	Patent License Agreement, by and between the Registrant and Peter Blume-Jensen, dated April 12, 2018
10.8*	Executive Employment Agreement, by and between the Registrant and Peter Blume-Jensen, dated October 5, 2020
10.9*	Employment Offer Letter Agreement, by and between the Registrant and Erick Gamelin, dated February 26, 2021
10.10*	Employment Offer Letter Agreement, dated October 5, 2020, and Letter Amendment to Employment Offer Letter Agreement, dated August 5, 2022, by and between the Registrant and Eric Devroe
10.11*	Non-Employee Director Compensation Policy
21.1*	List of Subsidiaries
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm
23.2*	Consent of Cooley LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)
107*	Filing Fee Table

Certain schedules to this agreement have been omitted in accordance with Item 601(a)(5) of Regulation S-K. A copy of any omitted schedules will be furnished supplementally to the SEC upon request.

† Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

* Previously filed.

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(c) Filing Fee Table.

The information required to be furnished by paragraph (c) of this Item is incorporated herein by reference to Exhibit 107.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has 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. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Watertown, Commonwealth of Massachusetts, on this 8th day of November, 2022.

ACRIVON THERAPEUTICS, INC.

By: /s/ Peter Blume-Jensen
Peter Blume-Jensen, M.D., Ph.D.
Chief Executive Officer and President

POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Peter Blume-Jensen Peter Blume-Jensen, M.D., Ph.D.	Chief Executive Officer, President and Chairman of the Board *(Principal Executive Officer)*	November 8, 2022
/s/ Rasmus Holm-Jorgensen Rasmus Holm-Jorgensen	Chief Financial Officer *(Principal Financial and Accounting Officer)*	November 8, 2022
* Derek DiRocco, Ph.D.	Director	November 8, 2022
* Kristina Masson, Ph.D.	Executive Vice President, Business Operations, Director	November 8, 2022
* Sharon Shacham, Ph.D., M.B.A.	Director	November 8, 2022
* Michael Tomsicek, M.B.A.	Director	November 8, 2022

*By: /s/ Peter Blume-Jensen
Peter Blume-Jensen
Attorney-in-Fact