

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended **June 30, 2023**

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: **001-41551**

**Acrivon Therapeutics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**82-5125532**

(I.R.S. Employer  
Identification No.)

**480 Arsenal Way, Suite 100**

**Watertown, Massachusetts**

(Address of principal executive offices)

**02472**

(Zip Code)

**Registrant's telephone number, including area code: (617) 207-8979**

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of August 8, 2023, the registrant had 22,072,916 shares of common stock, \$0.001 par value per share, outstanding.

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## Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or the Quarterly Report, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, 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 Investigational New Drug, or IND, submissions, initiation of clinical trials and timing of expected clinical results for our lead drug candidate, 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;
- 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 proprietary precision medicine platform, Acrivon Predictive Precision Proteomics, or AP3, 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 and the expected closing of our sale of common stock pursuant to the exercise of the underwriters’ option to purchase additional shares granted in connection with our initial public offering;
- 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 use of proceeds from our initial public offering and the concurrent private placement;
- 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.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, and results of operations. The outcome of the events described in these forward-looking statements is subject to risks and uncertainties, including the factors described in “Part II, Item 1A. Risk Factors” and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking

statements contained in this Quarterly Report. The results, events, and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events, or circumstances could differ materially from those described in the forward-looking statements.

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

The forward-looking statements contained in this Quarterly Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in or expressed by, and you should not place undue reliance on, our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments.

Unless the context otherwise requires, all references in this Quarterly Report to “we,” “us,” “our,” “our company,” and “Acrivon” refer to Acrivon Therapeutics, Inc. and its subsidiaries.

## Summary Risk Factors

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as more fully described in “Part II, Item 1A. Risk Factors” of this Quarterly Report on Form 10-Q. Below are some of these risks, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects:

- We are a clinical stage biopharmaceutical company and 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.
- 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 business substantially depends upon the successful clinical development of drug candidates using our AP3 platform and OncoSignature™, or 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.
- We are highly dependent on the success of 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.
- The regulatory approval processes of the U.S. Food and Drug Administration, or 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 operations and 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.
- Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval or licensure of and commercialize our drug candidates and affect the prices we, or they, may obtain.
- 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.
- 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 precision 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ACRIVON THERAPEUTICS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(UNAUDITED)

(in thousands, except share and per share data)

	June 30, 2023	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 38,074	\$ 29,519
Short-term investments	112,880	98,232
Prepaid expenses and other current assets	2,328	4,344
Total current assets	153,282	132,095
Property and equipment, net	1,975	2,092
Operating lease right-of-use assets	4,384	4,770
Long-term investments	—	41,881
Restricted cash	408	388
Total assets	<u>\$ 160,049</u>	<u>\$ 181,226</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,267	\$ 904
Accrued expenses and other current liabilities	4,997	4,886
Operating lease liabilities, current	753	726
Total current liabilities	7,017	6,516
Operating lease liabilities, long-term	3,848	4,235
Total liabilities	<u>10,865</u>	<u>10,751</u>
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized as of June 30, 2023 and December 31, 2022, respectively; 0 shares issued and outstanding as of June 30, 2023 and December 31, 2022.	—	—
Common stock, par value \$0.001; 500,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 22,068,660 and 21,920,402 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively.	22	22
Additional paid-in capital	232,291	226,580
Accumulated other comprehensive loss	(427)	(95)
Accumulated deficit	(82,702)	(56,032)
Total stockholders' equity	<u>149,184</u>	<u>170,475</u>
Total liabilities and stockholders' equity	<u>\$ 160,049</u>	<u>\$ 181,226</u>

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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Operating expenses:				
Research and development	\$ 10,521	\$ 4,077	\$ 20,279	\$ 10,145
General and administrative	4,999	1,848	9,634	2,992
Total operating expenses	<u>15,520</u>	<u>5,925</u>	<u>29,913</u>	<u>13,137</u>
Loss from operations	<u>(15,520)</u>	<u>(5,925)</u>	<u>(29,913)</u>	<u>(13,137)</u>
Other income (expense):				
Other income, net	1,606	105	3,243	97
Total other income, net	<u>1,606</u>	<u>105</u>	<u>3,243</u>	<u>97</u>
Net loss	<u>\$ (13,914)</u>	<u>\$ (5,820)</u>	<u>\$ (26,670)</u>	<u>\$ (13,040)</u>
Net loss per share—basic and diluted	<u>\$ (0.63)</u>	<u>\$ (3.29)</u>	<u>\$ (1.22)</u>	<u>\$ (7.37)</u>
Weighted-average common stock outstanding—basic and diluted	<u>21,971,032</u>	<u>1,769,561</u>	<u>21,945,940</u>	<u>1,769,561</u>
Comprehensive loss:				
Net loss	\$ (13,914)	\$ (5,820)	\$ (26,670)	\$ (13,040)
Other comprehensive loss:				
Unrealized loss on available-for-sale investments, net of tax	(436)	—	(332)	—
Comprehensive loss	<u>\$ (14,350)</u>	<u>\$ (5,820)</u>	<u>\$ (27,002)</u>	<u>\$ (13,040)</u>

*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' EQUITY (DEFICIT)**  
**(UNAUDITED)**  
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2022</b>	21,920,402	\$ 22	\$ 226,580	\$ (95)	\$ (56,032)	\$ 170,475
Exercise of common stock options	232	—	—	—	—	—
Stock-based compensation expense	—	—	2,646	—	—	2,646
Unrealized gain on available-for-sale investments, net of tax	—	—	—	104	—	104
Net loss	—	—	—	—	(12,756)	(12,756)
<b>Balance at March 31, 2023</b>	<u>21,920,634</u>	<u>\$ 22</u>	<u>\$ 229,226</u>	<u>\$ 9</u>	<u>\$ (68,788)</u>	<u>\$ 160,469</u>
Exercise of common stock options	148,026	—	379	—	—	379
Stock-based compensation expense	—	—	2,686	—	—	2,686
Unrealized loss on available-for-sale investments, net of tax	—	—	—	(436)	—	(436)
Net loss	—	—	—	—	(13,914)	(13,914)
<b>Balance at June 30, 2023</b>	<u>22,068,660</u>	<u>\$ 22</u>	<u>\$ 232,291</u>	<u>\$ (427)</u>	<u>\$ (82,702)</u>	<u>\$ 149,184</u>

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balance at December 31, 2021</b>	27,471,911	\$ 122,518	1,769,561	\$ 2	\$ 1,054	\$ (24,865)	\$ (23,809)
Stock-based compensation expense	—	—	—	—	40	—	40
Net loss	—	—	—	—	—	(7,220)	(7,220)
<b>Balance at March 31, 2022</b>	<u>27,471,911</u>	<u>\$ 122,518</u>	<u>1,769,561</u>	<u>\$ 2</u>	<u>\$ 1,094</u>	<u>\$ (32,085)</u>	<u>\$ (30,989)</u>
Stock-based compensation expense	—	—	—	—	233	—	233
Net loss	—	—	—	—	—	(5,820)	(5,820)
<b>Balance at June 30, 2022</b>	<u>27,471,911</u>	<u>\$ 122,518</u>	<u>1,769,561</u>	<u>\$ 2</u>	<u>\$ 1,327</u>	<u>\$ (37,905)</u>	<u>\$ (36,576)</u>

*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)

	<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (26,670)	\$ (13,040)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	254	123
Stock-based compensation expense	5,332	273
Non-cash lease expense	386	359
Net amortization of premiums and accretion of discounts on investments	(1,901)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,016	(2,496)
Accounts payable	363	449
Accrued expenses and other liabilities	111	410
Operating lease liabilities	(360)	(320)
Net cash used in operating activities	<u>(20,469)</u>	<u>(14,242)</u>
<b>Cash flows from investing activities:</b>		
Purchases of short-term and long-term investments	(16,963)	—
Proceeds from maturities of short-term investments	45,765	—
Purchases of property and equipment	(137)	(1,489)
Net cash provided by (used in) investing activities	<u>28,665</u>	<u>(1,489)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	379	—
Payments of deferred offering costs	—	(11)
Net cash provided by (used in) financing activities	<u>379</u>	<u>(11)</u>
Net increase (decrease) in cash, cash equivalents, and restricted cash	8,575	(15,742)
Cash, cash equivalents and restricted cash at beginning of period	29,907	99,991
Cash, cash equivalents and restricted cash at end of period	<u>\$ 38,482</u>	<u>\$ 84,249</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ —	\$ 424
Deferred offering costs in accounts payable and accrued expenses	\$ —	\$ 213
<b>Reconciliation of cash, cash equivalents, and restricted cash:</b>		
Cash and cash equivalents	\$ 38,074	\$ 83,861
Restricted cash	408	388
Total cash, cash equivalents, and restricted cash	<u>\$ 38,482</u>	<u>\$ 84,249</u>

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

**ACRIVON THERAPEUTICS, INC.**  
**NOTES TO THE 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 precision 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**

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.

The Company has incurred recurring losses since its inception, including net losses of \$26.7 million and \$13.0 million for the six months ended June 30, 2023, and 2022, respectively. As of June 30, 2023 and December 31, 2022 the Company had an accumulated deficit of \$82.7 million and \$56.0 million, respectively. 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.

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, and most recently, through an initial public offering (“IPO”) and concurrent private placement. Upon the closing of the Company’s IPO on November 17, 2022, only common stock remains issued and outstanding.

The Company expects that its existing cash, cash equivalents and investments of \$151.0 million as of June 30, 2023, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 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, considering the current interest rate environment. 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.

**Initial Public Offering, Reverse Stock Split and Concurrent Private Placement**

On November 17, 2022, the Company closed its IPO, pursuant to which it issued and sold 7,550,000 shares of its common stock at a public offering price of \$12.50 per share for gross proceeds of \$94.4 million. In connection with the IPO, the Company granted the underwriters a 30-day option to purchase 1,132,500 additional shares of common stock. On December 14, 2022, the underwriters partially exercised the option to purchase 1,035,540 additional shares. The sale pursuant to the exercise of the underwriters’ option to purchase additional shares closed on December 16, 2022, upon which the Company issued 1,035,540 shares of common stock for gross proceeds of \$12.9 million. The Company received aggregate net proceeds from the IPO, including the exercise by the underwriters of their option to purchase additional shares, of \$99.8 million, after deducting underwriting discounts and commissions of \$7.5 million, but before deducting offering expenses payable by the Company of \$3.6 million.

In connection with the IPO, the Company effected a 1-for-2.466 reverse stock split of the Company’s common stock and adjusted the ratio at which the Company’s preferred stock is convertible into common stock, the number of shares available for issuance under the 2019 Stock Incentive Plan (“2019 Plan”) and the number of options and exercise prices of options granted under the 2019 Plan as a result of the 1-for-2.466 reverse stock split. Accordingly, all common shares, stock options, and per share information presented in the

accompanying condensed consolidated financial statements and notes thereto have been adjusted, where applicable, to reflect the reverse stock split on a retroactive basis for all periods presented. The per share par value and authorized number of shares of the Company's common stock were not adjusted as a result of the reverse stock split.

Upon the closing of the IPO, all of the Company's then-outstanding shares of convertible preferred stock converted into 11,140,262 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

The Company also completed a private placement which closed concurrently with the IPO, in which the Company issued and sold 400,000 shares of its common stock at \$12.50 per share to Chione Limited, an existing investor of the Company (the "Concurrent Private Placement"). The Company received aggregate net proceeds of \$4.7 million from the Concurrent Private Placement, after deducting the placement agent fee.

## **2. Summary of Significant Accounting Policies**

The significant accounting policies and estimates used in the preparation of the accompanying condensed consolidated financial statements are described in the Company's audited consolidated financial statements for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC"), on March 28, 2023. There have been no material changes in the Company's significant accounting policies during the six months ended June 30, 2023, except as noted below.

### ***Basis of Presentation and Consolidation***

The accompanying unaudited condensed 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 statement of the Company's financial position as of June 30, 2023 and the results of its operations for the three and six months ended June 30, 2023 and 2022 and its cash flows for the six months ended June 30, 2023 and 2022. The condensed balance sheet as of December 31, 2022 was derived from audited annual financial statements but does not include all disclosures required by U.S. GAAP.

The results for the three and six months ended June 30, 2023 are not necessarily indicative of results to be expected for the full year or for any other subsequent interim period.

### ***Investments***

The Company classifies all investments with an original maturity of greater than three months and less than one year upon purchase as available-for-sale. Available-for-sale securities are recorded at fair value based upon market prices at period end, with the unrealized gains and losses reported in other comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income in the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value due to credit-related factors on available-for-sale securities are included in other income (expense), net in the consolidated statements of operations and comprehensive loss. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income in the consolidated statements of operation.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in the consolidated statements of operations. For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net income (loss). For available-for-sale securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income, net through an allowance account. There have been no impairment or credit losses recognized during any of the periods presented.

## Recently Adopted Accounting Pronouncements

### ASU 2016-13, Financial Instruments—Credit Losses

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2020-02 and ASU 2020-03 (collectively, "Topic 326"). Topic 326 significantly changes the impairment model for most financial assets and certain other instruments. Topic 326 requires immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets, which will generally result in earlier recognition of allowances for credit losses on loans and other financial instruments. The measurement is based on relevant information, including historical experience, current conditions and reasonable and supportable forecasts that affect the collectability of the reported amount and requires disclosure requirements related to credit risks. The Company adopted this accounting standard as of January 1, 2023, with no material impact on its condensed consolidated financial statements and related disclosures.

### 3. Investments

The following table summarizes the amortized cost and estimated fair value of the Company's U.S. Treasury securities and U.S. government-sponsored enterprise securities, which are considered to be available-for-sale investments and were included in short-term investments as of June 30, 2023 and in short-term investments and long-term investments as of December 31, 2022 on the condensed consolidated balance sheets (in thousands):

	June 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	\$ 9,748	\$ —	\$ (61)	\$ 9,687
U.S. government-sponsored enterprise securities	103,559	1	(367)	103,193
	<u>\$ 113,307</u>	<u>\$ 1</u>	<u>\$ (428)</u>	<u>\$ 112,880</u>

  

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Short-term investments:</b>				
U.S. Treasury securities	\$ 32,174	\$ 3	\$ (34)	\$ 32,143
U.S. government-sponsored enterprise securities	66,106	68	(85)	66,089
<b>Long-term investments:</b>				
U.S. Treasury securities	7,242	—	(4)	7,238
U.S. government-sponsored enterprise securities	34,686	—	(43)	34,643
	<u>\$ 140,208</u>	<u>\$ 71</u>	<u>\$ (166)</u>	<u>\$ 140,113</u>

Certain short-term debt securities with original maturities of less than 90 days are included in cash and cash equivalents on the condensed consolidated balance sheets and are not included in the tables above. As of June 30, 2023 and December 31, 2022, all short-term investments had contractual maturities within one year. As of December 31, 2022, all long-term investments had contractual maturities between one to two years.

The aggregate fair value of available-for-sale securities held by the Company in an unrealized loss position for less than 12 months as of June 30, 2023 was \$105.4 million. The unrealized losses on the Company's investments of \$0.4 million and \$0.2 million as of June 30, 2023 and December 31, 2022, respectively, were caused by interest rate increases which resulted in the decrease in market value of these securities. There were no available-for-sale securities in a continuous unrealized loss position for greater than 12 months. Because the decline in fair value is attributable to changes in interest rates and not credit quality, and because the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be maturity, there are no allowances for credit losses as of June 30, 2023.

#### 4. Fair Value Measurement

The following tables present information about the Company's financial assets measured at fair value on a recurring basis (in thousands):

Assets:	Total	Fair Value Measurements at June 30, 2023 Using:		
		Level 1	Level 2	Level 3
<b>Cash equivalents:</b>				
Money market funds	\$ 14,807	\$ 14,807	\$ —	\$ —
<b>Short-term investments:</b>				
U.S. Treasury securities	9,687	9,687	—	—
U.S. government-sponsored enterprise securities	103,193	—	103,193	—
Total assets	\$ 127,687	\$ 24,494	\$ 103,193	\$ —

  

Assets:	Total	Fair Value Measurements at December 31, 2022 Using:		
		Level 1	Level 2	Level 3
<b>Cash equivalents:</b>				
Money market funds	\$ 24,082	\$ 24,082	\$ —	\$ —
<b>Short-term investments:</b>				
U.S. Treasury securities	32,143	32,143	—	—
U.S. government-sponsored enterprise securities	66,089	—	66,089	—
<b>Long-term investments:</b>				
U.S. Treasury securities	7,238	7,238	—	—
U.S. government-sponsored enterprise securities	34,643	—	34,643	—
Total assets	\$ 164,195	\$ 63,463	\$ 100,732	\$ —

The Company classifies its money market funds and U.S. Treasury securities as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets without any valuation adjustment. The Company classifies its U.S. government-sponsored enterprise securities as Level 2 assets under the fair value hierarchy as these assets have been valued using information obtained through a third-party pricing service as of the balance sheet date, using observable market inputs that may include trade information, broker or dealer quotes, bids, offers, or a combination of these data sources.

During the six months ended June 30, 2023 and year ended December 31, 2022, 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 values due to the short-term nature of these amounts.

#### 5. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Laboratory and computer equipment	\$ 2,477	\$ 2,340
Furniture and fixtures	172	172
Total property and equipment	2,649	2,512
Less: accumulated depreciation	(674)	(420)
Property and equipment, net	\$ 1,975	\$ 2,092

Depreciation expense related to property and equipment for each of the three months and six months ended June 30, 2023 was \$0.1 million and \$0.3 million, respectively. Depreciation expense related to property and equipment for each of the three months and six months ended June 30, 2022 was \$0.1 million and \$0.1 million, respectively.

## 6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Accrued compensation and benefits	\$ 2,062	\$ 2,662
Accrued research and development expenses	2,053	790
Accrued legal, accounting and other professional fees	820	648
Accrued other	62	44
Accrued offering costs	—	673
Deferred sublease income	—	69
<b>Total accrued expenses and other current liabilities</b>	<b>\$ 4,997</b>	<b>\$ 4,886</b>

## 7. Leases

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 an option to extend the term for an additional three years. Lease payments are 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 was recognized on a straight-line basis over the term of the sublease agreement. Sublease rent income, including common area maintenance charges, was \$0.2 million for the three months ended June 30, 2022, and \$0.2 million and \$0.4 million for each of the six months ended June 30, 2023 and 2022, 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 statements 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.

The following table summarizes the presentation of the Company's operating leases on its condensed consolidated balance sheets (in thousands):

Leases	Balance sheet classification	June 30, 2023	December 31, 2022
<b>Assets:</b>			
Operating lease assets	Operating lease right-of-use assets	\$ 4,384	\$ 4,770
<b>Total lease assets</b>		<b>\$ 4,384</b>	<b>\$ 4,770</b>
<b>Liabilities:</b>			
Current:			
Operating lease liabilities	Operating lease liability, current	\$ 753	\$ 726
Noncurrent:			
Operating lease liabilities	Operating lease liability, long-term	3,848	4,235
<b>Total lease liabilities</b>		<b>\$ 4,601</b>	<b>\$ 4,961</b>

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 statements of operations and comprehensive loss were as follows (in thousands):

Lease cost	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating lease cost	\$ 286	\$ 286	\$ 572	\$ 571
Variable lease cost	152	188	248	262
Sublease income	—	(134)	(134)	(269)
Total lease cost	\$ 438	\$ 340	\$ 686	\$ 564

As of June 30, 2023 and December 31, 2022, the weighted-average remaining lease term for operating leases was 4.8 years and 5.3 years, respectively, and the weighted-average discount rate was 7.87% and 7.86%, respectively. Cash paid for amounts included in the measurement of lease liabilities was \$0.5 million for the six months ended June 30, 2023.

Future minimum annual lease commitments under the Company's non-cancelable operating leases as of June 30, 2023 were as follows (in thousands):

Year ended December 31,	Amount
2023 (remaining 6 months)	\$ 538
2024	1,098
2025	1,131
2026	1,165
2027	1,200
Thereafter	404
Total lease payments	5,536
Less: interest	(935)
Present value of operating lease liabilities	\$ 4,601

## 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 the consolidated balance sheet.

In January 2021, upon effectiveness of the license agreement and stock issuance agreement with Eli Lilly and Company ("Lilly") (collectively, 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 obligation to issue capital stock in a subsequent financing to Lilly in order to maintain a specified, single-digit ownership percentage of the Company upon specified conditions 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.

Upon the closing of the Company’s IPO on November 17, 2022, all outstanding shares of Preferred Stock converted into 11,140,262 shares of common stock.

## 9. Stockholders' Equity

Prior to the IPO, the voting, dividend and liquidation rights of the holders of the Company’s common stock were subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock as set forth above and described in the Company’s final prospectus for the IPO filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on November 16, 2022.

In October 2022, the Board approved the amended and restated certificate of incorporation, which was filed upon the closing of the IPO and which authorized the Company to issue up to 10,000,000 shares of preferred stock, with a par value of \$0.001. There are no shares of preferred stock issued or outstanding as of June 30, 2023.

As of June 30, 2023 and December 31, 2022, the Company’s Amended and Restated Certificate of Incorporation authorized the Company to issue 500,000,000 shares of common stock with a par value of \$0.001.

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 Amended and Restated Certificate of Incorporation.

As of June 30, 2023 and December 31, 2022, the Company had reserved the following shares of common stock for the potential exercise of stock options, vesting of restricted stock units, as well as the remaining shares available for issuance under the 2022 Stock Option and Incentive Plan (the “2022 Plan”), the 2022 Employee Stock Purchase Plan (the “2022 ESPP”), and the 2023 Inducement Plan (the “Inducement Plan”):

	June 30, 2023	December 31, 2022
Options to purchase common stock	3,130,630	3,300,935
Unvested restricted stock units	1,805,055	1,787,152
Remaining shares reserved for future issuance	2,503,004	733,636
Total	<u>7,438,689</u>	<u>5,821,723</u>

## 10. Stock-Based Compensation

### 2022 Equity Incentive Plan

In October 2022, the Board adopted, and in November 2022 its stockholders approved, the 2022 Plan, which replaced the 2019 Plan and became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company’s IPO. No further shares were issued under the 2019 Plan as of the effective date of the 2022 Plan. 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 (“RSUs”) and other stock-based awards. The number of shares initially reserved for issuance under the 2022 Plan was 5,606,723, which is the sum of: (i) 2,555,271 new shares, plus (ii) the number of shares that remained available for issuance under the 2019 Plan at the time the 2022 Plan became 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 shall automatically increase beginning 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 of common stock 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.

As of June 30, 2023, there were 1,618,800 shares reserved for future issuance under the 2022 Plan.

### 2022 Employee Stock Purchase Plan

In October 2022, the Board adopted, and in November 2022 its stockholders approved, the 2022 ESPP, which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. 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.

No shares of the Company's common stock were issued and no stock-based compensation expense was recognized during the six months ended June 30, 2023 related to the 2022 ESPP. As of June 30, 2023, there were 434,204 shares reserved for future issuance under the 2022 ESPP.

### 2023 Inducement Plan

In June 2023, the Board adopted the Inducement Plan to facilitate the granting of equity awards as an inducement material to new employees joining the Company. The Inducement Plan is administered by the compensation committee of the Board. The Board reserved 450,000 common shares of the Company for issuance under the Inducement Plan. The only persons eligible to receive awards under the Inducement Plan are individuals who are new employees and satisfy the standards for inducement grants under Nasdaq Listing Rule 5635(c)(4) or 5635(c)(3), as applicable. The terms of the Inducement Plan are identical to the terms of the 2022 Plan, except that no incentive stock options shall be awarded under the Inducement Plan.

No shares of the Company's common stock were issued and no stock-based compensation expense was recognized during the six months ended June 30, 2023 related to the Inducement Plan.

### 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 for the six months ended June 30, 2023:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	3,300,935	\$ 6.29	9.26	\$ 18,346
Granted	109,789	14.45		
Exercised	(148,258)	2.56		
Forfeited or canceled	(131,836)	5.22		
Outstanding as of June 30, 2023	3,130,630	\$ 6.80	8.41	\$ 19,503
Vested and expected to vest as of June 30, 2023	3,130,630	\$ 6.80	8.41	\$ 19,503
Vested and exercisable as of June 30, 2023	914,489	\$ 2.64	6.68	\$ 9,439

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 aggregate intrinsic value of options exercised during the six months ended June 30, 2023 was \$1.5 million. There were no options exercised during the six months ended June 30, 2022.

The weighted-average grant date fair value of the Company's stock options granted during the three months ended June 30, 2023 and 2022 was \$8.92 and \$2.59 per option, respectively. The weighted-average grant date fair value of the Company's stock options granted during the six months ended June 30, 2023 and 2022 was \$10.49 and \$2.54 per option, respectively. As of June 30, 2023, there

was \$11.8 million of unrecognized stock-based compensation expense related to stock option grants. The Company expects to recognize this amount over a weighted-average period of 2.9 years.

The total fair value of options vested during the three months ended June 30, 2023 and 2022 was \$0.5 million \$0.1 million, respectively. The total fair value of options vested during the six months ended June 30, 2023 and 2022 was \$0.8 million and \$0.2 million, respectively.

### RSUs

The Company has granted RSUs with service vesting based conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. They are legally issued and outstanding. These restrictions lapse according to the time-based vesting of each award.

A summary of the RSU activity during the six months ended June 30, 2023 is as follows:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2022	1,787,152	\$ 12.49
Granted	25,781	15.10
Vested	—	—
Forfeited	(7,878)	12.50
Unvested at June 30, 2023	<u>1,805,055</u>	<u>\$ 12.53</u>

The Company granted RSUs under the 2022 Plan, which typically vest over four years.

The weighted-average grant date fair value of the Company's RSUs granted during the three and six months ended June 30, 2023 was \$11.97 and \$15.10 per RSU, respectively. No RSUs were granted during the three or six months ended June 30, 2022. As of June 30, 2023, there was \$18.2 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over a weighted-average period of 2.6 years.

### 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):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
General and administrative	\$ 2,075	\$ 82	\$ 4,095	\$ 95
Research and development	611	151	1,237	178
Total stock-based compensation expense	<u>\$ 2,686</u>	<u>\$ 233</u>	<u>\$ 5,332</u>	<u>\$ 273</u>

### 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):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<b>Numerator:</b>				
Net loss attributable to common stockholders—basic and diluted	\$ (13,914)	\$ (5,820)	\$ (26,670)	\$ (13,040)
<b>Denominator:</b>				
Weighted-average number of common shares used in net loss per share—basic and diluted	<u>21,971,032</u>	<u>1,769,561</u>	<u>21,945,940</u>	<u>1,769,561</u>
Net loss per share—basic and diluted	<u>\$ (0.63)</u>	<u>\$ (3.29)</u>	<u>\$ (1.22)</u>	<u>\$ (7.37)</u>

The Company's potentially dilutive securities, which include Preferred Stock, stock options and RSUs, 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, 2023 and 2022 because including them would have had an anti-dilutive effect:

	June 30,	
	2023	2022
Convertible preferred stock (as converted to common stock)	—	27,471,911
Options to purchase common stock	3,130,630	2,072,851
Unvested restricted stock units	1,805,055	—

## 12. Commitments and Contingencies

### Leases

The Company's commitments under its operating leases are described in Note 7.

### License Agreement

In January 2021, the Company entered into the Lilly Agreement, 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.

As of June 30, 2023, no milestone payments or royalties have been incurred related to the Lilly Agreement.

### 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 June 30, 2023, the Company has made aggregate payments of \$3.8 million to Akoya. The Company recorded no milestone expense and expense of \$1.5 million during the three and six months ended June 30, 2023, respectively.

### 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 each of its directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or services as directors or executive officers. 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, 2023 and December 31, 2022.

### ***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. We are not currently party to any material legal proceedings and are not aware of any pending or threatened legal proceedings against us that we believe could have an adverse effect on our business, operating results or financial condition.

### ***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, 2023, the Company has not made any contributions to the 401(k) Plan.

## Item 2. 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 unaudited consolidated financial statements and related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q, and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2022 and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 28, 2023. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, 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 Quarterly Report on Form 10-Q, 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. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to “Acrivon,” the “Company,” “we,” “us,” and “our” refer to Acrivon Therapeutics, Inc. and its 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 precision 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 precision 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. On May 8, 2023, ACR-368 was granted two Fast Track designations from the U.S. Food and Drug Administration for the investigation of ACR-368 monotherapy for patients with OncoSignature-positive platinum-resistant ovarian cancer and endometrial cancer.

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.

In November 2022, we completed our initial public offering, or IPO, pursuant to which we issued and sold 7,550,000 shares of our common stock for net proceeds. Additionally, we completed our concurrent private placement, or the Concurrent Private Placement, pursuant to which we issued and sold 400,000 shares of our common stock. In connection with the IPO, in December 2022, the underwriters partially exercised their option to purchase 1,035,540 additional shares. The sale pursuant to the exercise of the underwriters’ option to purchase additional shares closed on December 16, 2022, upon which we issued 1,035,540 additional shares of common stock. We received aggregate net proceeds from our IPO, including the partial exercise by the underwriters of their option to purchase additional shares, and the Concurrent Private Placement, of \$104.5 million, after deducting underwriting discounts and commissions and the placement agent fee, but before deducting offering expenses payable by us of \$3.6 million.

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, all of which fully converted into common stock upon the closing of the IPO, and most recently, with aggregate net proceeds from our IPO, including the partial exercise by the underwriters of their option to purchase additional shares, and Concurrent Private Placement of \$104.5 million, after deducting underwriting discounts and commissions and the placement agent fee, but before deducting offering expenses payable by the Company.

We have incurred operating losses since inception. Our net losses for the six months ended June 30, 2023 and 2022 were \$26.7 million and \$13.0 million, respectively. Our net loss for the year ended December 31, 2022 was \$31.2 million. As of June 30, 2023, we had an accumulated deficit of \$82.7 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 obligations as a public reporting company.

We are incurring and expect to continue 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 COVID-19 and the war 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, 2023, we had cash, cash equivalents and investments of \$151.0 million. We believe that our existing cash, cash equivalents and investments as of June 30, 2023, will enable us to fund our operating expenses and capital expenditure requirements into 2025. 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.”

### ***Companion Diagnostic Agreement***

In June 2022, we entered into a companion diagnostic agreement, or the Akoya 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 August 11, 2023, development milestones have been achieved under the agreement, resulting in payments of \$3.8 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.

## **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 could potentially include (but not be limited to) 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 have 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.

Research and development costs are expensed as incurred. We recognize external development costs as related goods are delivered or services are performed. Significant judgments and estimates are made in determining the accrued expense balances at the end of any reporting period.

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

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.

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.

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 expenses.

We anticipate that our general and administrative expenses will continue to 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 (Expense), Net*

Other income, net primarily consists of interest income, which is earned on cash equivalents and investments, and amortization of premiums and accretion of discounts to maturity for available-for-sale debt securities.



## Results of Operations

### Comparison of the Three Months Ended June 30, 2023 and 2022

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

	Three Months Ended June 30,		Change
	2023	2022	
Operating expenses:			
Research and development	\$ 10,521	\$ 4,077	\$ 6,444
General and administrative	4,999	1,848	3,151
Total operating expenses	\$ 15,520	\$ 5,925	\$ 9,595
Loss from operations	\$ (15,520)	\$ (5,925)	\$ (9,595)
Other income (expense):			
Other income, net	1,606	105	1,501
Total other income, net	1,606	105	1,501
Net loss	\$ (13,914)	\$ (5,820)	\$ (8,094)

### Research and Development Expenses

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

	Three Months Ended June 30,		Change
	2023	2022	
Direct research and development expenses by program:			
ACR-368	\$ 4,659	\$ 681	\$ 3,978
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	3,373	1,751	1,622
Other drug discovery programs	1,568	1,358	210
Facilities, supplies and other	921	287	634
Total research and development expenses	\$ 10,521	\$ 4,077	\$ 6,444

Research and development expenses were \$10.5 million for the three months ended June 30, 2023, compared to \$4.1 million for the three months ended June 30, 2022. The increase of \$6.4 million was primarily due to:

- a \$4.0 million increase in costs related to the continued progression of the ACR-368 clinical trial and related activities;
- a \$1.6 million increase in personnel-related costs, including \$0.5 million of stock-based compensation expense, primarily due to an increase in headcount in support of research activities and progression of our clinical stage ACR-368 program;
- a \$0.2 million increase in costs related to preclinical drug discovery activities as a result of increased efforts toward identifying drug candidates; and
- a \$0.6 million increase in facilities, supplies and other expenses, primarily due to an increase in headcount and related research activities, as well as the cessation of sublease rent income, which had been 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):

	Three Months Ended June 30,		Change
	2023	2022	
Personnel related (including stock-based compensation)	\$ 3,219	\$ 1,057	\$ 2,162
Legal and professional fees	1,355	631	724
Facilities, supplies and other	425	160	265
Total general and administrative expenses	\$ 4,999	\$ 1,848	\$ 3,151

General and administrative expenses were \$5.0 million for the three months ended June 30, 2023, compared to \$1.8 million for the three months ended June 30, 2022. The increase of \$3.2 million was primarily due to:

- a \$2.2 million increase in payroll and employee-related expenses, including \$2.0 million of stock-based compensation expense;
- a \$0.7 million increase in legal, accounting and professional fees due to additional costs associated with operating as a public company; and
- a \$0.3 million increase in facilities, supplies, and other expenses, primarily due to an increase in headcount.

#### *Total Other Income (Expense), Net*

Total other income, net was \$1.6 million for the three months ended June 30, 2023, compared to total other expense, net of \$0.1 million for the three months ended June 30, 2022. The change of \$1.5 million is primarily attributable to an increase in interest income earned on our investments.

#### **Comparison of the Six Months Ended June 30, 2023 and 2022**

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

	Six Months Ended June 30,		Change
	2023	2022	
Operating expenses:			
Research and development	\$ 20,279	\$ 10,145	\$ 10,134
General and administrative	9,634	2,992	6,642
Total operating expenses	\$ 29,913	\$ 13,137	\$ 16,776
Loss from operations	\$ (29,913)	\$ (13,137)	\$ (16,776)
Other income (expense):			
Other income, net	3,243	97	3,146
Total other income, net	3,243	97	3,146
Net loss	\$ (26,670)	\$ (13,040)	\$ (13,630)

#### *Research and Development Expenses*

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

	Six Months Ended June 30,		Change
	2023	2022	
Direct research and development expenses by program:			
ACR-368	\$ 8,932	\$ 4,101	\$ 4,831
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	6,660	2,950	3,710
Other drug discovery programs	3,096	2,529	567
Facilities, supplies and other	1,591	565	1,026
Total research and development expenses	\$ 20,279	\$ 10,145	\$ 10,134

Research and development expenses were \$20.3 million for the six months ended June 30, 2023, compared to \$10.1 million for the six months ended June 30, 2022. The increase of \$10.1 million was primarily due to:

- a \$4.8 million increase in costs related to the continued progression of the ACR-368 clinical trial and related activities;
- a \$3.7 million increase in personnel-related costs, including \$1.1 million of stock-based compensation expense, primarily due to an increase in headcount in support of research activities and progression of our clinical stage ACR-368 program;
- a \$0.6 million increase in costs related to preclinical drug discovery activities as a result of increased efforts toward identifying drug candidates; and
- a \$1.0 million increase in facilities, supplies and other expenses, primarily due to an increase in headcount and related research activities, as well as the cessation of sublease rent income, which had been 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):

	Six Months Ended June 30,		Change
	2023	2022	
Personnel related (including stock-based compensation)	\$ 6,522	\$ 1,724	\$ 4,798
Legal and professional fees	2,347	939	1,408
Facilities, supplies and other	765	329	436
Total general and administrative expenses	<u>\$ 9,634</u>	<u>\$ 2,992</u>	<u>\$ 6,642</u>

General and administrative expenses were \$9.6 million for the six months ended June 30, 2023, compared to \$3.0 million for the six months ended June 30, 2022. The increase of \$6.6 million was primarily due to:

- a \$4.8 million increase in payroll and employee-related expenses, including \$4.0 million of stock-based compensation expense;
- a \$1.4 million increase in legal, accounting and professional fees due to additional costs associated with operating as a public company; and
- a \$0.4 million increase in facilities, supplies, and other expenses, primarily due to an increase in headcount.

## Total Other Income (Expense), Net

Total other income, net was \$3.2 million for the six months ended June 30, 2023, compared to total other income, net of \$0.1 million for the six months ended June 30, 2022. The change of \$3.1 million is primarily attributable to an increase in interest income earned on our investments.

## 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, 2023, we had \$151.0 million in cash, cash equivalents and investments, and we had an accumulated deficit of \$82.7 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, all of which fully converted into common stock upon the closing of the IPO, and \$104.5 million in net proceeds from the IPO and the Concurrent Private Placement. We believe that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements into 2025.

### Other Liquidity Matters

We have a banking relationship with SVB. On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. On March 12, 2023, the Treasury Department announced that the FDIC would complete its resolution of SVB in a manner that fully protects all depositors. We had access to all of our money starting March 13, 2023. As a result, we did not incur any losses nor do we anticipate any future losses with respect to such cash balances. As of August 11, 2023, we have maintained full access to and have begun the process of diversifying our holdings.

### Cash Flows

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

	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	\$ (20,469)	\$ (14,242)
Net cash provided by (used in) investing activities	28,665	(1,489)
Net cash provided by (used in) financing activities	379	(11)
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ 8,575</u>	<u>\$ (15,742)</u>

### *Net Cash Used in Operating Activities*

Net cash used in operating activities was \$20.5 million for the six months ended June 30, 2023, compared to net cash used in operating activities of \$14.2 million for the six months ended June 30, 2022. The increase in cash used in operating activities of \$6.3 million was primarily driven by an increase in net loss of \$13.6 million, partially offset by a \$5.1 million increase in non-cash stock-based compensation expense.

### *Net Cash Provided by (Used in) Investing Activities*

Net cash provided by investing activities was \$28.7 million for the six months ended June 30, 2023, resulting primarily from an increase in investment maturities, partially offset by an increase in investment purchases and purchases of property and equipment.

Net cash used in investing activities was \$1.5 million for the six months ended June 30, 2022, resulting from purchases of property and equipment.

### *Net Cash Provided by (Used in) Financing Activities*

Net cash provided by financing activities was \$0.4 million for the six months ended June 30, 2023, resulting from the exercise of stock options.

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.

### **Funding Requirements**

As of June 30, 2023, our cash, cash equivalents and investments were \$151.0 million. We believe that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements into 2025. 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, we expect to continue to incur additional costs associated with operating as a public 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 but not limited to:

- 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; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, current or future drug candidates, if any.

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, 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 \$5.5 million as of June 30, 2023. Of the \$5.5 million, \$1.1 million is due in 12 months or less. See Note 7 in our unaudited condensed consolidated financial statements in this Quarterly Report 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.

#### *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. As of August 11, 2023, development milestones have been achieved under our companion diagnostic agreement, resulting in payments of \$3.8 million by us to Akoya.

#### *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 cancelable 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 financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no significant changes to our critical accounting policies from those described in our Annual Report on Form 10-K.

## **Recent Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations and cash flows is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

## **Internal Control Over Financial Reporting**

In connection with the audit of our consolidated financial statements for the years ended December 31, 2022 and 2021, 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.”

## **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 will remain an emerging growth company until the earlier to occur of (1) the last day of our fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenues of at least \$1.235 billion or (c) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our common shares that is held by non-affiliates exceeds \$700 million as of the last day of our second quarter, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue 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.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

Under SEC rules and regulations, because we are considered to be a “smaller reporting company,” we are not required to provide the information required by this item in this report.

### **Item 4. Controls and Procedures.**

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

The term “disclosure controls and procedures” as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2023. Prior to the completion of our IPO in November 2022, we had been a private company and therefore had not designed or maintained internal controls over financial reporting commensurate with the financial reporting requirements of an SEC registrant. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2023 because of the material weaknesses in our internal control over financial reporting described below.

#### **Previously Identified Material Weaknesses in Internal Control Over Financial Reporting**

A “material weakness” is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Prior to the completion of our IPO in November 2022, we had not designed or maintained internal controls over financial reporting commensurate with the financial reporting requirements of an SEC registrant. We previously disclosed in our 2022 Annual Report on Form 10-K the following material weaknesses, which have not been fully remediated as of June 30, 2023:

- 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 which have not been fully remediated as of June 30, 2023:

- We did not design and maintain effective controls over the preparation and review of account reconciliations and journal entries necessary to achieve complete, accurate and timely financial accounting, reporting and disclosures.
- 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 and identified prior to our initial public offering in November 2022 resulted in material misstatement to our consolidated financial statements. However, the material weaknesses described above could result in a material 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. Notwithstanding such material weaknesses, our Chief

Executive Officer and Chief Financial Officer have concluded that our consolidated financial statements in this Quarterly Report on Form 10-Q present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented, in conformity with U.S. generally accepted accounting principles.

### **Remediation Progress of Previously Identified Material Weaknesses**

With the oversight of the Audit Committee of our Board of Directors, we have continued throughout the quarter ended June 30, 2023 to dedicate significant resources and efforts to improve our control environment and to take steps to remediate our material weaknesses identified above by implementing changes to our internal control over financial reporting.

#### *Remediation Actions Completed In Prior Quarters*

The following remediation efforts were taken prior to the quarter ended June 30, 2023:

- Hired finance and accounting personnel, including Chief Financial Officer;
- Engaged third-party professionals to assist with technical accounting assessments, financial reporting assistance and timeliness of identification, assessment, and response to the risk of material misstatement;
- Established more robust accounting policies and procedures, such as implementing and documenting controls over the preparation and review of account reconciliations and journal entries;
- Performed a gap analysis to identify where new process controls are needed and to enhance existing controls to accurately build financial accounting, reporting, and disclosure procedures to document routine reconciliations and journal entries in a timely fashion;
- Further formalized the design and operational effectiveness of controls over balance sheet account reconciliations and journal entries; and
- Designed and implemented an upgrade to our financial systems to support key processes and controls.

#### *Additional and Ongoing Remediation Actions Taken During the Current Quarter*

The following remediation efforts were taken in the quarter ended June 30, 2023 and continue to address the identified material weaknesses and enhance our overall financial control environment:

- Continued execution of information technology general controls for information systems that are relevant to the preparation of its financial statements; and
- Continued execution of controls previously designed and implemented to maintain an effective control environment commensurate with the financial reporting requirements of a public company, and to respond to the risks of material misstatement.

While we believe that the measures described above remediate the identified material weaknesses and strengthen our internal control over financial reporting, the implemented and enhanced controls would need to operate for a sufficient period of time to demonstrate that the material weaknesses are fully remediated. Specifically, we believe that the information technology general controls for information systems that are relevant to the preparation of our financial statements are sufficiently designed and are in place. We further believe that based upon the above remediation efforts that we have sufficiently improved our effective control environment to be commensurate with the financial reporting requirements of a public company and are also able to respond to the risks of material misstatement. We believe these controls are designed effectively and are in place as of June 30, 2023, and we are now monitoring to ensure that such newly implemented controls are operating for a sufficient period of time to demonstrate effectiveness and remediation. For these remaining material weaknesses, as the implemented and enhanced controls have not yet operated for a sufficient period of time, management has concluded that the material weaknesses cannot be considered remediated as of June 30, 2023. We are committed to continuing to improve our internal control process and will continue to review, optimize, and enhance our financial reporting controls and procedures.

We can give no assurance that additional material weaknesses in our internal control over financial reporting will not be identified in the future. Further, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

### **Remediation of Previously Identified Material Weakness**

We had a previously reported material weakness in internal control over financial reporting related to complete, accurate and timely financial accounting, reporting and disclosures, including related to the identification of and accounting for certain non-routine,



unusual, or complex transactions in a timely fashion, as disclosed in Part II, Item 9A in our 2022 Annual Report on Form 10-K. To address the accounting for certain non-routine, unusual or complex transactions, we designed and implemented new control activities such as:

- Established controls to identify and account for certain non-routine, unusual or complex transactions in a timely fashion;
- Upon completion of our IPO, our convertible preferred stock was converted into common stock resulting in a less complex capital structure, which assisted with our remediation process; and
- Adopted certain robust policies and procedures, inclusive of new charters, investment policy, disclosure committee and other guidelines and processes to allow the timely identification and assessment of transactions and financial statement disclosures.

Based on the actions taken, we determined that this aspect of the previously reported material weakness has been remediated as of June 30, 2023.

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

Management determined that, as of June 30, 2023, the remediation of a previously-identified material weakness represented a change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f)) that occurred during the quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Inherent Limitations on Effectiveness of Controls**

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

**Item 1. 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.

## Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

### 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 loss was \$31.2 million for the year ended December 31, 2022, and \$26.7 million and \$13.0 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of \$82.7 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, and more recently, \$92.4 million, or \$104.5 million following the sale pursuant to the exercise of the underwriters' option to purchase additional shares, in each case after deducting underwriting discounts and commissions and the placement agent fee, but before deducting offering expenses payable by the Company, from our IPO and Concurrent Private Placement. 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.

***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, 2023, we had cash, cash equivalents and investments of \$151.0 million. We believe that our existing cash, cash equivalents and investments as of June 30, 2023, will be sufficient to fund our operating expenses and capital expenditure requirements into 2025. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. 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 but not limited to:

- 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 (PHE), 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 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, the ownership interest of our existing stockholders 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

***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 conceptually the same for all of our drug candidates. Accordingly, a failure in any one program may decrease trust in our AP3 platform. 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 an 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.

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. Travel restrictions and other uncertainties may continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. 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. On February 2, 2022, the FDA announced that it would resume domestic surveillance inspections across all product areas on February 7, 2022.

On May 11, 2023, the COVID-19 PHE declared under the Public Health Service (PHS) Act expired. It is unclear how the FDA's policies and guidance will impact any inspections of our facilities, including our clinical trial sites. During the COVID-19 PHE, 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 COVID-19 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.

***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.



***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.

Moreover, Congress has recently enacted changes to the Accelerated Approval Program that could impact our ability to obtain Accelerated Approval, or increase the burdens associated with postmarketing requirements in the event we do obtain Accelerated Approval. In particular, the FDA must specify certain conditions for required postapproval studies for products that receive Accelerated Approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the drug is approved. The FDA may also require postapproval studies to be underway at the time of Accelerated Approval or within a specified time period following Accelerated Approval for such drugs, and must explain any instances where it does not require such studies.

Any delay in obtaining, or inability to obtain, approval through the Accelerated Approval Program, or any issues in maintaining approval granted under the Accelerated Approval Program, would delay or prevent commercialization of our products, and would materially adversely affect our business, financial condition, results of operations and prospects.

***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 but not limited to:

- 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 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 COVID-19, 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. The 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 but not limited to:

- 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 COVID-19, 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 but not limited to:

- regulatory authorities may withdraw approval of or seize the drug;
- we may be required to recall a product, or change the way the drug is administered to patients, or conduct additional clinical trials;
- 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. See the description of risks under the heading “Risks Related to Ownership of our Common Stock and our Status as a Public Company” 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 business co-development pharma partnerships leveraging our AP3 platform for patient responder identification or uncovering of resistance mechanisms to drug candidates or 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. 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 extensive preclinical evaluation, 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 COVID-19 global pandemic.***

Our business and operations may be adversely affected by the effects of the COVID-19 virus, which was declared by the World Health Organization as a global pandemic. On May 11, 2023, the COVID-19 PHE declared under the PHS Act expired. While the PHE has ended, COVID-19 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 COVID-19 or other PHEs 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 require or enhance 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 COVID-19 to date, we may experience related disruptions in the future that could severely impact our clinical trials, including but not limited to:

- 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 COVID-19 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 in response to COVID-19 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 effect of COVID-19 continues to rapidly evolve. The extent to which COVID-19 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, 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 COVID-19 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, as well as 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. See “Part I, Item 1, Business—Government Regulation—Healthcare and Privacy Law and Regulation and Healthcare Reform” of our Annual Report on Form 10-K for the year ended December 31, 2022, for more information on the healthcare laws and regulations that may affect our ability to operate.

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 but not limited to:

- 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;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our products.

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 prevent or delay marketing approval or licensure of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval or licensure. In the United States, the biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA-approved product. For example, the Inflation Reduction Act (IRA), which was signed into law on August 16, 2022, allows Medicare to: beginning in 2026, establish a "maximum fair price" for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the Centers for Medicare and Medicaid Services (CMS); and, beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation, among other reforms. CMS has recently taken steps to implement the IRA; first, by releasing a list of 43 Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA for the time period of July 1, 2023 to September 30, 2023 on June 9, 2023; and, on June 30, 2023, issuing guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026. It is unclear how future regulatory actions to implement the IRA, as well as the outcome of pending litigation against the IRA, may affect our products and future profitability. Reductions in reimbursement levels may also negatively impact the prices we receive or the frequency with which our products are prescribed or administered, with any reduction in reimbursement from Medicare or other government programs potentially resulting in a similar reduction in payments from private payors. See "Part I, Item 1, Business—Government Regulation—Healthcare Reform" of our Annual Report on Form 10-K for the year ended December 31, 2022, for more information on specific healthcare reform measures that may affect our business.

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 lengthen 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 but not limited to:

- different regulatory requirements for drug and companion diagnostic trials and 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.

In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a recent decision by the U.S. Court of Appeals for the Eleventh Circuit. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, results of operations, financial condition and prospects.

***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.

On May 8, 2023, ACR-368 was granted two Fast Track designations from the U.S. Food and Drug Administration for the investigation of ACR-368 monotherapy for patients with OncoSignature-positive platinum-resistant ovarian cancer and endometrial cancer. We may seek Fast Track designation for 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. Sponsors may have greater interactions with the FDA and marketing applications filed by sponsors of products in Fast Track development may qualify for priority review and rolling 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 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 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 ACR-368 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 partner 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 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 but not limited to:

- 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 will also have less oversight and control of a third party sales force than we would with an employed sales force. 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 precision 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), 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. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, government authorities and 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 sufficient to cover our costs. Reimbursement may affect the demand for, or the price of, any drug candidate for which we obtain marketing approval or licensure. 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 or licensure.

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, but are not limited to:

- 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, EVP of Business Operations, a member of our board of directors, 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 June 30, 2023, we had 50 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 or disclosure to us of unauthorized activities that violate the requirements of the FDCA, regulations of the FDA or similar foreign regulatory authorities;
- healthcare fraud and abuse in violation of U.S. and foreign laws and regulations;
- violations of U.S. federal securities laws relating to trading in our common stock; and
- failures to report financial information or data accurately.

In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations regulate 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. While we have adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. 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. We and our third party vendors frequently detect, contain and respond to data security incidents. 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 or may unintentionally receive 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. State privacy laws in particular are evolving, with more than a dozen new state privacy laws passed in recent years, along with additional health privacy specific laws. These laws may further increase our compliance obligations, and potential legal privacy risks. For example, Washington recently passed the My Health My Data Act, which has a broader scope than HIPAA and includes a private right of action. 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 the EU, the EU 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 (SCCs) including a requirement to carry out a transfer impact assessment (TIA) which could increase our costs and our ability to efficiently process personal data from the EEA. However, on July 10, 2023, the European Commission adopted its adequacy decision for the new EU-US Data Privacy Framework (i.e., the replacement to the EU-US Privacy Shield) to legitimize the transfer of personal data from the EU to companies that self-certify to the Framework in the US. Further, companies continuing to rely on SCCs for transfers from the EU to US can leverage the analysis in the European Commission’s adequacy decision as support for their TIAs.

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, the GDPR’s data protection obligations continue to apply to the UK in substantially unvaried form under the so-called “UK GDPR” which exists alongside the UK Data Protection Act 2018 which in turn, implements certain derogations in the UK GDPR into UK law. The UK GDPR provides for significant fines of up to the greater of £17.5 million or 4% of global turnover. As a result, we are potentially exposed to two parallel data protection regimes, each of which authorizes fines and the potential for divergent enforcement actions. It should be noted that the UK GDPR also prohibits the transfer of personal data from the UK to other countries that are not recognized as having “adequate” data protection laws, including the U.S., in a similar manner to the EU. In addition, the UK Government has published its own form of SCCs, known as the International Data Transfer Agreement and International Data Transfer Addendum to the new EU SCCs. The UK Information Commissioner’s Office has also published its version of the TIA and revised guidance on international transfers, although companies may choose to either use the EU style or UK style TIA. In terms of international data transfers between the UK and U.S., the U.S. Department of Commerce has announced that companies will also immediately be able to self-certify to the UK Extension of the EU-US Data Privacy Framework, but that the UK component will not be live until the finalization of the separate and ongoing UK-U.S. adequacy process.

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 the CCPA took effect on January 1, 2020, and the amendments thereto under the CPRA took effect on January 1, 2023. 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 and sharing 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 CPRA imposed 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 the California Privacy Protection Agency to implement and enforce the law, which could result in increased privacy and information security enforcement. As a result of the CPRA going into effect earlier this year, 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 amendments under the CPRA may increase our compliance costs and potential liability.

Multiple states have followed California to legislate comprehensive privacy laws with data privacy rights. For example, Virginia passed the Virginia Consumer Data Protection Act (“VCDPA”), which went into effect on January 1, 2023 and affords consumers similar rights to the CCPA, along with additional rights, such as the right to opt-out of processing for profiling and targeted advertising purposes. Additionally, the Colorado Privacy Act (“CPA”) and Connecticut Personal Data Privacy and Online Monitoring Act

("CTDPA") went into effect on July 1, 2023 and the Utah Privacy Rights Act will go into effect later this year, and each impose similar obligations to those in the CCPA and VCDPA. While these new laws generally include exemptions for HIPAA-covered and clinical trial data, they impact the overall privacy landscape. Several other states have followed suit and passed similar legislation which will go into effect in the coming years. Further, additional privacy laws that are similar in nature 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, and other US state privacy laws, as well as 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. For a more detailed description of this agreement, see Note 8 to our consolidated financial statements included elsewhere in this Quarterly Report.

Disputes may also arise between us and our current licensor or future licensors regarding intellectual property subject to a license agreement, including but not limited to:

- 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 Ownership of our Common Stock and our Status as a Public Company**

#### ***An active trading market for our common stock may not continue to be developed or sustained.***

Prior to our IPO, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Global Market, an active trading market for our shares may not continue to develop or be sustained. If an active market for our common stock does not continue to develop or be sustained, it may be difficult for you to sell shares of our common stock at an attractive price or at all.

In addition, concentration of ownership by our existing stockholders may result in fewer shares being actively traded in the public market because these stockholders may be restricted from selling such shares under applicable securities laws, which could reduce the liquidity of the market and the available public float for our shares of common stock.

#### ***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 but not limited to:

- 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 COVID-19, 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. As of August 8, 2023, we had 22,072,916 shares of common stock outstanding. This includes 7,550,000 shares sold in our IPO, which may be resold in the public market unless purchased by our affiliates. Substantially all of the remaining shares of common stock outstanding after the IPO are restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict transfers until at least May 13, 2023, which is 180 days after the date of the final prospectus for our IPO. 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 on behalf of the underwriters. 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 have filed a registration statement on Form S-8 under the Securities Act registering shares subject to outstanding stock options issued under the 2019 Stock Incentive Plan, or the 2019 Plan, and shares of common stock reserved for issuance under the 2022 Stock Option and Incentive Plan, or the 2022 Plan, and the 2022 Employee Stock Purchase Plan, or the 2022 ESPP. Both the 2022 Plan and the 2022 ESPP provide for annual automatic increases in the shares reserved for issuance under the plans which could result in additional dilution to our stockholders. Shares registered under these registration statements on Form S-8 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, the lock-up period with respect to the IPO, and the restrictions of Rule 144 in the case of our affiliates.

***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.

***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 a majority of our outstanding common stock. 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 our IPO or, if earlier, (i) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 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 Quarterly Report 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 have broad discretion in the use of our cash, cash equivalents and investments, including the net proceeds from our IPO and the Concurrent Private Placement, and may invest or spend the cash, cash equivalents and investments in ways with which you do not agree and in ways that may not yield a return.***

We have broad discretion over the use of our cash, cash equivalents and investments, including the net proceeds from our IPO and the Concurrent Private Placement. You may not agree with our decisions, and our use of the cash, cash equivalents and investments may not yield any return. Our failure to apply our cash, cash equivalents and investments 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. Stockholders will not have the opportunity to influence our decisions on how to use our cash, cash equivalents and investments.

***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 our IPO, we had been a private company and therefore had not designed or maintained internal controls over financial reporting commensurate with the financial reporting requirements of an SEC registrant.

We identified material weaknesses in our internal control over financial reporting related to a lack of design and maintenance of an effective control environment commensurate with the financial reporting requirements of a public company and the lack of design and maintenance of effective controls in response to the risks of material misstatement. These material weaknesses contributed to additional material weaknesses related to our failure to 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, and controls over information technology general controls for information systems that are relevant to the preparation of its financial statements.

None of the material weaknesses described in Item 4 and above resulted in material misstatement to our consolidated financial statements. However, the material weaknesses described in Item 4 and above could result in a material 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 our IPO, we had 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 are detailed in Item 4, "Controls and Procedures," of this document.

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 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 to produce accurate financial statements on a timely basis needs to be periodically re-evaluated and is costly and time-consuming. 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 our IPO, we began 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 beginning in our annual report on Form 10-K for the year ended December 31, 2023.

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, 2022, we had approximately \$21.5 million federal net operating loss carryforwards and \$20.9 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 our IPO, together with private placements and other transactions that have occurred since our inception, may have triggered 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 NOL carryforwards 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. More recently, the Inflation Reduction Act of 2022 enacted further changes to federal income tax law. 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. 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, including as a result of recent events in the U.S. banking sector. 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. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, higher



inflation, bank failures or continued unpredictable and unstable market conditions. 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 have incurred and will continue to 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 have incurred and will continue to 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.***

We are 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.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

### **Use of Proceeds from our Public Offering of Common Stock and Concurrent Private Placement**

On November 9, 2022, our Registration Statement on Form S-1, as amended (File No. 333-267911), was declared effective in connection with our IPO, pursuant to which we sold an aggregate of 7,550,000 shares of our common stock at a price to the public of \$12.50 per share. In connection with the IPO, we granted the underwriters a 30-day option to purchase 1,132,500 additional shares of our common stock. Jefferies LLC, Cowen and Company, LLC and Piper Sandler & Co. acted as joint book-running managers.

The IPO closed on November 17, 2022. On December 14, 2022, the underwriters partially exercised the option to purchase 1,035,540 additional shares. The sale pursuant to the exercise of the underwriters' option to purchase additional shares closed on December 16, 2022, upon which we issued 1,035,540 shares of common stock for additional gross proceeds of \$12.9 million. We received aggregate net proceeds from the IPO, including the exercise by the underwriters of their option to purchase additional shares, of \$99.8 million, after deducting underwriting discounts and commissions of \$7.5 million, but before deducting offering expenses payable by us of \$3.6 million. We also completed a private placement which closed concurrently with the IPO, in which we issued and sold 400,000 shares of our common stock at \$12.50 per share to Chione Limited, an existing investor. We received aggregate net proceeds of \$4.7 million, after deducting the placement agent fee. In connection with our IPO and Concurrent Private Placement, no payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates or to our affiliates. As of June 30, 2023, we had used \$18.7 million of the net proceeds from the IPO. We have invested the net proceeds from

the offering in money market funds, short-term investments, and long-term investments. There has been no material change in the planned use of proceeds from our IPO and Concurrent Private Placement as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on November 16, 2022.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
10.1†^	<a href="#">Amended and Restated Employment Agreement, dated as of May 30, 2023, by and between Acrivon Therapeutics, Inc. and Kristina M. Masson (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41551), filed with the Securities and Exchange Commission on June 5, 2023).</a>
10.2*†	<a href="#">Second Amendment to OncoSignature Companion Diagnostic Agreement, by and between Acrivon Therapeutics, Inc. and Akoya Biosciences, Inc., dated June 19, 2023.</a>
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1+	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2+	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\* Filed herewith.

+ This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

† Certain exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K and will be furnished on a supplemental basis to the Securities and Exchange Commission upon request.

^ Indicates management contract or compensatory plan.





**SECOND AMENDMENT TO ONCOSIGNATURE COMPANION  
DIAGNOSTIC AGREEMENT**

This **SECOND AMENDMENT TO ONCOSIGNATURE COMPANION DIAGNOSTIC AGREEMENT** (the “**Second Amendment**”) is made and entered into as of June 19, 2023 (the “**Second Amendment Effective Date**”) by and between:

**Acrivon Therapeutics, Inc.**, a Delaware corporation with its principal place of business at 480 Arsenal Way, Suite 100, Watertown, MA 02472 (“**Acrivon**”), and

**Akoya Biosciences, Inc.**, a Delaware corporation with its principal place of business at 100 Campus Drive, 6th floor, Marlborough, MA 01752 (“**Akoya**”).

Acrivon and Akoya are each referred to individually as a “**Party**” and together as the “**Parties.**”

**WHEREAS**, Acrivon and Akoya are parties to that certain Oncosignature Companion Diagnostic Agreement, dated June 17, 2022, as amended on December 21, 2022 (the “**Agreement**”), under which the Parties are collaborating to develop, validate, obtain regulatory approval for, and commercialize a companion diagnostic test for use with Prexasertib; and

**WHEREAS**, the Parties now wish to amend certain terms of the Agreement, as set forth in more detail below.

**NOW THEREFORE**, in consideration of the mutual promises and agreement set forth herein, and for other good and valuable considerations, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Schedule 3.5 of the Agreement is hereby deleted and replaced in its entirety with Schedule 3.5 attached to this Second Amendment as Exhibit A.

2. This Second Amendment amends the terms of the Agreement as expressly provided above, and the Agreement, as so amended and including all of its other terms and provisions that are not amended, remains in full force and effect. Capitalized terms used but not defined herein shall have the meanings set forth in the Agreement. The validity, performance, construction, and effect of this Second Amendment shall be governed by and construed under the substantive laws of the State of Delaware, without regard to conflicts of law rules that would cause the application of the laws of another jurisdiction. This Second Amendment may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties have executed this Second Amendment in duplicate originals by their proper officers as of the Second Amendment Effective Date.

ACRIVON THERAPEUTICS, INC.

AKOYA BIOSCIENCES, INC.

By: /s/ Eric Devroe

By: /s/ Johnny Ek

Name: Eric Devroe

Name: Johnny Ek

Date: June 19, 2023

Date: June 20, 2023

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**Exhibit A**

**Schedule 3.5**

**Development Milestones; Development Milestone Payments**

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**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Rasmus Holm-Jorgensen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Acrivon Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2023

By: \_\_\_\_\_ /s/ Rasmus Holm-Jorgensen

**Rasmus Holm-Jorgensen**  
**Chief Financial Officer**

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code ( 18 U.S.C. § 1350), Peter Blume-Jensen, Chief Executive Officer of Acrivon Therapeutics, Inc. (the "Company") hereby certifies that, to the best of his knowledge:

- (1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 11, 2023

**IN WITNESS WHEREOF**, the undersigned has set his hands hereto as of the 11th day of August 2023.

By: \_\_\_\_\_ /s/ Peter Blume-Jensen

**Peter Blume-Jensen, M.D., Ph.D.**  
**Chief Executive Officer and President**

\*This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Acrivon Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code ( 18 U.S.C. § 1350), Rasmus Holm-Jorgensen, Chief Financial Officer of Acrivon Therapeutics, Inc. (the "Company") hereby certifies that, to the best of his knowledge:

- (1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 11, 2023

**IN WITNESS WHEREOF**, the undersigned has set his hands hereto as of the 11th day of August 2023.

By: \_\_\_\_\_ /s/ Rasmus Holm-Jorgensen

**Rasmus Holm-Jorgensen  
Chief Financial Officer**

\*This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Acrivon Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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