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DELTA REPORT

10-Q

IKNA - IKENA ONCOLOGY, INC.

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	701
CHANGES	137
DELETIONS	242
ADDITIONS	322

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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 September 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: 001-40287

IKENA ONCOLOGY, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-1697316**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
645 Summer Street, Suite 101 Boston, MA	**02210**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 273-8343

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

	Trading

Title of each class	Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	IKNA	The 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	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 1, 2023 November 1, 2023, the registrant had 42,301,253 48,258,111 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

Page

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve risks, uncertainties, and other factors that may cause actual results, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan,"

"potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion studies or trials and related preparatory work, the period during which the results of the trials will become availab and our research and development programs;
- our ability to efficiently discover and develop product candidates;
- our ability and the potential to successfully manufacture our drug substances and product candidates for preclini use, for clinical trials, and on a larger scale, for commercial use, if approved;
- the ability and willingness of our third-party strategic collaborators to continue research and development activit relating to our development candidates and product candidates;
- our ability to obtain funding for our operations necessary to complete further development and commercializatic of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our future expenses, revenue, capital requirements, and our needs for additional financing;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of product candidates and any oth approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and relevant foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturin cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- our use of proceeds from our initial public offering and underwritten registered offering;
- developments relating to our competitors and our industry;
- the effect of the COVID-19 pandemic, pandemics, epidemics, or a similar pandemic, epidemic, or any outbreak of a infectious disease, including mitigation efforts and economic effects, on any of the foregoing or other aspects of c business operations, including but not limited to our preclinical studies and clinical trials and any future studies or trials;

- the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, economic sanctions, bank failures, regional conflicts around the world, and economic slowdo or recessions that may result from such developments which could harm our research and development efforts a well as the value of our common stock and our ability to access capital markets; and
- other risks and uncertainties, including those under the caption "Risk Factors."

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or into which we may enter.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Summary of the Material and Other Risks Associated with Our Business

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We are a targeted oncology company with a limited operating history.
- We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for foreseeable future.
- We have no products approved for commercial sale and have not generated any revenue from product sales.
- We will require additional capital to finance our operations, which may not be available on acceptable terms, or at If we are unable to raise capital when needed or on terms acceptable to us, we would be forced to delay, reduce o eliminate some of our product development programs or commercialization efforts.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquis rights to our technologies or product candidates.
- We have never successfully completed any clinical trials for our oncology programs, and we may be unable to do s for any product candidates we develop. Certain of our oncology programs are still in preclinical development and may never advance to clinical development.
- Our programs are focused on the development of oncology therapeutics for patients with genetically defined or

biomarker-driven cancers, which is a rapidly evolving area of science, and the approach we are taking to discover a develop drugs is novel and may never lead to approved or marketable products.

- Clinical product development involves a lengthy and expensive process, with an uncertain outcome.
- The COVID-19 pandemic, Pandemics, epidemics, or a similar pandemic, epidemic, or any outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- If the market opportunities for our programs and product candidates are smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.
- We rely on third parties to conduct our Phase 1 clinical trials of IK-930 and IK-175 and expect to rely on third parties to conduct clinical trials for our other targeted oncology programs, including IK-595, as well as investigator-sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties comply with regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory appr for or commercialize our product candidates and our business could be substantially harmed.
- We have entered into collaborations and may enter into additional collaborations in the future, and we might not realize the anticipated benefits of such collaborations.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- Our future success depends on our ability to retain key executives and experienced scientists and to attract, retai and motivate qualified personnel.
- The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The material and other risks summarized above should be read together with the text of the full risk factors below and with the other information set forth in this Quarterly Report, including our consolidated financial statements and the related notes, as well as with other documents that we file with the SEC. If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above, or described in full below, are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

IKENA ONCOLOGY, INC.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	June 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
Assets				
Current assets:				
Cash and cash equivalents	$ 70,868	$ 59,919	$ 121,277	$ 59,919
Marketable securities	86,444	97,028	75,656	97,028
Prepaid expenses and other current assets	3,334	3,063	3,701	3,063
Total current assets	160,646	160,010	200,634	160,010
Property and equipment, net	2,875	3,205	2,633	3,205
Right-of-use asset	4,575	5,255	7,993	5,255
Deposits and other assets	3,668	3,789	4,075	3,789
Total assets	$ 171,764	$ 172,259	$ 215,335	$ 172,259
Liabilities and Stockholders' Equity				
Liabilities, Convertible Preferred Stock and Stockholders' Equity				
Current liabilities:				
Accounts payable	$ 1,772	$ 2,093	$ 3,950	$ 2,093
Accrued expenses and other current liabilities	6,455	8,343	11,193	8,343
Operating lease liability	1,937	1,907	3,469	1,907
Deferred revenue	1,844	9,160	659	9,160
Total current liabilities	12,008	21,503	19,271	21,503
Long-term portion of operating lease liability	3,056	3,787	8,023	3,787
Other long term liabilities			852	—

Total liabilities	15,064	25,290	28,146	25,290
Commitments and contingencies (Note 12)				
Convertible preferred stock				
Series A Non-Voting Convertible Preferred Stock, $0.001 par value -5,000,000 shares designated and 4,153,439 issued and outstanding as of September 30, 2023. No shares designated, issued and outstanding as of December 31, 2022			31,845	—
Stockholders' equity:				
Preferred Stock, $0.001 par value - 10,000,000 shares authorized as of June 30, 2023 and December 31, 2022; No shares issued and outstanding as of June 30, 2023 or December 31, 2022	—	—		
Common stock, $0.001 par value - 150,000,000 shares authorized and 42,299,478 issued and outstanding as of June 30, 2023 and 150,000,000 shares authorized and 36,257,493 issued and outstanding as of December 31, 2022	42	36		
Preferred stock, $0.001 par value - 10,000,000 shares authorized as of September 30, 2023 and December 31, 2022; No shares issued and outstanding as of September 30, 2023 or December 31, 2022			—	—
Common stock, $0.001 par value - 150,000,000 shares authorized and 44,104,672 issued and outstanding as of September 30, 2023 and 150,000,000 shares authorized and 36,257,493 issued and outstanding as of December 31, 2022			44	36
Additional paid-in capital	402,667	361,915	418,486	361,915
Accumulated other comprehensive loss	(456)	(763)	(290)	(763)
Accumulated deficit	(245,553)	(214,219)	(262,896)	(214,219)

Total stockholders' equity	156,700	146,969	155,344	146,969
Total liabilities and stockholders' equity	$ 171,764	$ 172,259		
Total liabilities, convertible preferred stock and stockholders' equity			$ 215,335	$ 172,259

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

IKENA ONCOLOGY, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
Statement of Operations								
Research and development revenue under collaboration agreement	$ 2,004	$ 382	$ 7,316	$ 3,766	$ 1,185	$ 6,402	$ 8,501	$ 10,168
Operating expenses:								
Research and development	15,172	15,488	30,723	29,831	14,654	18,850	45,378	48,682
General and administrative	5,322	5,845	10,598	11,848	6,034	5,428	16,632	17,276
Total operating expenses	20,494	21,333	41,321	41,679	20,688	24,278	62,010	65,958
Loss from operations	(18,490)	(20,951)	(34,005)	(37,913)	(19,503)	(17,876)	(53,509)	(55,790)
Other income (expense):								

Investment income	1,381	460	2,677	583	2,162	550	4,840	1,135
Other expense	(6)	—	(6)	—	(2)	(12)	(8)	(13)
Total other income, net	1,375	460	2,671	583	2,160	538	4,832	1,122
Net loss	($ (17,115)	($ (20,491)	($ (31,334)	($ (37,330)	($ (17,343)	($ (17,338)	($ (48,677)	($ (54,668)
Other comprehensive loss:								
Unrealized gain (loss) on marketable securities	35	(626)	(456)	(1,104)	166	(77)	(290)	(1,181)
Total comprehensive loss	($ (17,080)	($ (21,117)	($ (31,790)	($ (38,434)	($ (17,177)	($ (17,415)	($ (48,967)	($ (55,849)
Net loss per share:								
Net loss per share attributable to common stockholders basic and diluted	($ (0.44)	($ (0.57)	($ (0.83)	($ (1.03)	($ (0.40)	($ (0.48)	($ (1.23)	($ (1.51)
Weighted-average common stock outstanding, basic and diluted	39,292,710	36,160,851	37,783,486	36,118,415	43,437,844	36,258,074	39,688,984	36,165,143

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

IKENA ONCOLOGY, INC.

Condensed Consolidated Statement of Convertible Preferred Stock and Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity	Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					Shares	Amount	Shares	Amount				
Balance as of December 31, 2022	36,257,493	$ 36	$ 361,915	$ (763)	$ (214,219)	$ 146,969	—	—	36,257,493	$ 36	$ 361,915	$ (763)	$ (214,219)	$ 146,969
Stock-based compensation	—	—	2,000	—	—	2,000	—	—	—	—	2,000	—	—	2,000
Other comprehensive income	—	—	—	272	—	272	—	—	—	—	—	272	—	272
Net loss	—	—	—	—	(14,219)	(14,219)	—	—	—	—	—	—	(14,219)	(14,219)

Balance as of March 31, 2023	36,257,493	36	363,915	(491)	(228,438)	135,022	—	—	36,257,493	36	363,915	(491)	(228,438)	135,022
Issuance of common stock for underwritten registered offering, net of offering costs of $2.6 million	6,110,000	6	37,415		—	37,421	—	—	6,110,000	6	37,415	—	—	37,421
Repurchase of common stock	(97,500)	—	(663)		—	(663)	—	—	(97,500)	—	(663)	—	—	(663)
Stock-based compensation	—	—	1,879	—	—	1,879	—	—	—	—	1,879	—	—	1,879
Exercise of stock options	29,485	—	121	—	—	121	—	—	29,485	—	121	—	—	121
Other comprehensive income	—	—	—	35	—	35			—	—	—	35	—	35

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Net loss					(17,115)								(17,115)	
	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Balance as of June 30, 2023	42,299,478	$ 42	402,766,470	$ (456)	$ (53)	$ 0	—	—	42,299,478	42	402,766,470	$ (456)	$ (53)	$ 0
Issuance of preferred stock in connection with the Acquisition, net of issuance costs of $0.4 million							4,153,043	32,504						
Issuance of common stock in connection with the Acquisition, net of issuance costs of $1.0 million							—	—	1,800,650	2	140,000	—	—	140,002

Cash consideration paid to settle Pionyr restricted stock units, stock options, and unaccredited stockholders	—	(659)	—	—	(285)	—	—	(285)
Stock-based compensation	—	—	—	—	199	—	—	199
Exercise of stock options	—	—	454	—	15	—	—	15
Other comprehensive income	—	—	—	—	—	16	—	16
Net loss	—	—	—	—	—	—	(17,734)	(17,734)
Balance as of September 30, 2023	4,153,431	$ 459	44,104,648	$ 44	$ 41,848	$ (290)	$ (62,965)	$ 41,096

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					Shares	Amount				
Balance as of December 31, 2021	35,975,034	$ 36	$ 353,295	$ —	$ (145,438)	$ 207,893	35,975,034	$ 36	$ 353,295	$ —	$ (145,438)	$ 207,893
Stock-based compensation	—	—	1,900	—	—	1,900	—	—	1,900	—	—	1,900
Exercise of stock options	134,500	—	495	—	—	495	134,500	—	495	—	—	495
Other comprehensive loss	—	—	—	(478)	—	(478)	—	—	—	(478)	—	(478)
Net loss	—	—	—	—	(16,839)	(16,839)	—	—	—	—	(16,839)	(16,839)

Balance as of March 31, 2022	36,109,534		355,690	(478)	(16,293)	19,955	36,109,534		35,905,690	(478)	(16,293)	19,955
Stock-based compensation	—	—	1,955	—	—	1,955	—	—	1,955	—	—	1,955
Exercise of stock options	142,443	—	575	—	—	575	142,443	—	575	—	—	575
Other comprehensive loss	—	—	—	(626)	—	(626)	—	—	—	(626)	—	(626)
Net loss	—	—	—	—	(20,491)	(20,491)	—	—	—	—	(20,491)	(20,491)
Balance as of June 30, 2022	36,251,977	$ 36	358,220	(1,104)	(18,293)	17,684	36,251,977	36	35,908,220	(1,104)	(18,293)	17,684

Stock-based compensation	—	—	1,811	—	—	1,811
Exercise of stock options	5,516	—	24	—	—	24
Other comprehensive loss	—	—	—	(77)	—	(77)
Net loss	—	—	—	—	(17,338)	(17,338)
Balance as of September 30, 2022	36,257,493	$ 36	$ 55,036	$ (1,181)	$ (20,122)	$ 88,815

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

IKENA ONCOLOGY, INC.

Condensed Consolidated Statements of Cash Flows
(in thousands)

	Six Months Ended June 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cash flows from operating activities				
Net loss	$ (31,34)	$ (37,330)	$ (48,677)	$ (54,668)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation	473	328	715	541
Amortization of premiums and discounts on marketable securities	(1,132)	69	(1,709)	103
Stock-based compensation	3,879	3,855	5,877	5,666
Non-cash operating lease expense	681	628	1,152	953
Loss on disposal of property and equipment	5	173	5	173
Net realized loss on marketable securities			—	12
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	339	(2,036)	1,271	682
Accounts payable	(321)	952	(987)	(206)
Accrued expenses and other current liabilities	(2,011)	(693)	(5,308)	2,816
Lease liability	(701)	(623)	(1,333)	(954)
Deferred revenue	(7,316)	(3,765)	(8,501)	(10,168)
Deposits and other assets	(489)	(793)	(429)	(1,404)
Net cash flows used in operating activities	(37,927)	(39,235)	(57,924)	(56,454)
Cash flows from investing activities				
Purchases of property and equipment	(152)	(69)	(152)	(1,200)
Sale of property and equipment	4	—	4	—
Purchase of marketable securities	(47,050)	(174,996)	(65,217)	(189,863)
Sales and maturities of marketable securities	59,072	29,500	109,133	81,280

Net cash flows provided by (used in) investing activities	11,874	(145,565)	43,768	(109,783)
Cash flows from financing activities				
Cash and cash equivalents acquired in connection with the acquisition of Pionyr, net of issuance costs paid			39,970	—
Cash consideration paid in connection with the acquisition of Pionyr			(944)	—
Proceeds from issuance of common stock for underwritten registered offering, net of offering costs	37,544	—	37,421	—
Repurchase of common stock	(663)	—	(663)	—
Proceeds from exercise of stock options	121	1,070	136	1,094
Net cash flows provided by financing activities	37,002	1,070	75,920	1,094
Net increase (decrease) in cash and cash equivalents and restricted cash	10,949	(183,730)	61,764	(165,143)
Cash, cash equivalents and restricted cash, beginning of period	60,791	233,089	60,791	233,089
Cash, cash equivalents and restricted cash, end of period	$ 71,740	$ 49,359	$ 122,555	$ 67,946
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets				
Cash and cash equivalents	70,868		121,277	
	$ 8	$ 48,487	$ 7	$ 67,074
Restricted cash included in other assets	872	872	1,278	872
Cash, cash equivalents and restricted cash, end of period	71,740		122,555	
	$ 0	$ 49,359	$ 5	$ 67,946
Supplemental cash flow information				
Noncash investing and financing activities				
Purchases of property and equipment in accounts payable and accrued expenses	$ —	$ 943		
Underwritten registered offering costs in accrued expenses	$ 123	$ —		

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

IKENA ONCOLOGY, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Basis of Presentation

Ikena Oncology, Inc. (the "Company") is a targeted oncology company, focused on developing differentiated therapies for patients in need that target nodes of cancer growth, spread, and therapeutic resistance in the Hippo and RAS onco-signaling network. The Company's lead targeted oncology program, IK-930, is a TEAD1-selective Hippo pathway inhibitor, a known tumor suppressor pathway that also drives resistance to multiple targeted therapies. The Company's first program in the RAS pathways, pathway, IK-595, is molecular glue designed to trap MEK and RAF in an inactive complex, more completely inhibiting RAS signals than existing inhibitors. In addition, the Company is developing IK-175, an aryl hydrocarbon receptor ("AHR") antagonist in collaboration with Bristol-Myers Squibb Company ("Bristol-Myers Squibb"). The Company's focus on patient-driven development allows it to research both known and novel targets, with a shared guiding principle of aiming to address the unmet needs of biomarker-defined patient populations. Since the Company commenced operations in 2016, it has advanced multiple product candidates into clinical development. In addition, the Company has a robust discovery engine and portfolio of early stage targeted oncology programs. Across the entirety of its pipeline, the Company aims to utilize its depth of institutional knowledge and breadth of tools to efficiently develop the right drug using the right modality for the right patient.

Acquisition of Pionyr Therapeutics

The Company acquired Pionyr Immunotherapeutics, Inc., a Delaware corporation ("Pionyr"), pursuant to an Agreement and Plan of Merger, dated August 4, 2023 by and among the Company, Portsmouth Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub I"), Portsmouth Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Merger Sub II"), Pionyr, and Fortis Advisors LLC, as securityholder agent (the "Pionyr Acquisition Agreement"). Pursuant to the Pionyr Acquisition Agreement, Merger Sub I merged with and into Pionyr, after which Pionyr was the surviving corporation and became a wholly owned subsidiary of the Company (the "First Merger"). Immediately after the First Merger, Pionyr merged with and into Merger Sub II, after which Merger Sub II was the surviving entity (collectively with the First Merger, the "Acquisition").

Under the terms of the Pionyr Acquisition Agreement, at the closing, the Company issued to the stockholders of Pionyr 1,800,652 shares of its common stock (including 153,121 shares of its non-voting common stock), and 4,153,439 shares of Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"), which was a newly designated series of preferred stock that is intended to have economic rights equivalent to the Company's common stock, but with only

limited voting rights. The Series A Preferred Stock was converted to shares of the Company's common stock pursuant to stockholder approval at a special meeting of stockholders held on October 11, 2023. Each stockholder of Pionyr at the time of closing also received one contractual contingent value right ("CVR") for each share of Pionyr stock held at closing. The CVR entitles the holder to receive 50% of net proceeds, outside of royalties, for any potential monetization of Pionyr legacy programs within two years.

Basis of Presentation: The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial reporting. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the ASC Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying condensed consolidated financial statements and footnotes to the financial statements have been prepared on the same basis as the most recently audited annual financial statements and, in the opinion of management, reflect all normal recurring adjustments necessary for the fair presentation of the Company's financial position for the reported periods. The results of operations for any interim periods are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. These condensed consolidated financial statements should be read in conjunction with, the Company's audited consolidated financial statements for the year ended December 31, 2022, which were included in its Annual Report on Form 10-K that was filed with the Securities and Exchange Commission ("SEC") on March 14, 2023.

2. Summary of Significant Accounting Policies

Principles of Consolidation: The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Arrys Therapeutics, Inc. ("Arrys"), Ikena Oncology Securities Corporation, and Amplify Medicines, Inc, ("Amplify"). and Portsmouth Merger Sub II, LLC. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates: The preparation of the Company's financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the

financial statements and the reported amounts of revenue and expenses during the reporting period. Estimates and judgments are based on historical information and other market-specific or various relevant assumptions, including in certain circumstances, future projections, that management believes to be reasonable under the circumstances. Actual results could differ materially from estimates. Significant estimates and assumptions are used for, but not limited to the accruals for research and development expenses and research and development revenue under a collaboration agreement.

Summary of Significant Accounting Policies: The significant accounting policies and estimates used in the preparation of the accompanying 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 that was filed with the SEC on March 14, 2023. There have been no material changes in the Company's significant accounting policies during the six nine months ended June 30, 2023 September 30, 2023 except as discussed below.

Concentration of Credit Risk and of Significant Suppliers: Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, and marketable securities. Cash and cash equivalents are deposited with federally insured financial institutions in the United States and may, at times, exceed federally insured limits. The Company places marketable securities with a highly rated financial institution. Additionally, as of June 30, 2023 September 30, 2023, the Company has not experienced any credit related losses on accounts that hold the Company's cash, cash equivalents and marketable securities.

The Company is dependent on third-party manufacturers and clinical research organizations ("CROs") to supply products and provide services for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. The Company also relies on at least two CROs to conduct its clinical trials. The Company's programs could be adversely affected if a third-party manufacturer or a CRO is unable to successfully carry out their contractual obligations or meet expected deadlines. If a third-party manufacturer or a CRO needs to be replaced, the Company may not be able to complete its program development on its anticipated timelines and may incur additional expenses as a result, which could be significant.

Convertible Preferred Stock: The Company records shares of convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The Company applies the guidance in ASC 480-10-S99-3A, SEC Staff Announcement: Classification and Measurement of Redeemable Securities in determining the classification of preferred stock as stockholder's deficit or temporary equity.The Company classified convertible preferred stock as temporary equity in the accompanying consolidated statement of Convertible Preferred Stock and Stockholders' Equity due to terms that allow for redemption of the shares in cash upon certain events that are outside of the Company's control, including failure to obtain stockholder approval of the conversion of the Series A Preferred Stock. The Company did not accrete the value of the convertible preferred stock to the redemption values since a liquidation event was not considered probable prior to the conversion date.

Contingent Value Rights: The Company evaluates the CVR to determine if it qualifies as a derivative under ASC 815, Derivatives and Hedging. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date. Any changes in fair value are recorded as other income or expense for each reporting period. Derivative instrument liabilities are classified in the balance sheet as

current or non-current based on whether or not net-cash settlement of the derivative instrument is probable within the next 12 months from the balance sheet date.

The Company determined that certain contingent payments under the Acquisition qualified for the scope exception under ASC 815, and as such, were not recorded as a derivative on the balance sheet as of September 30, 2023. Upon resolution of the CVR, the Company will recognize the payment consistent with the guidance in ASC 450. As of September 30, 2023, the contingent consideration cannot be reasonably estimated, and the contingency was not resolved.

Recent Accounting Pronouncements: From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial statements and disclosures.

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3. Fair Value Measurements

The following table presents information about the Company's financial assets measured or disclosed at fair value by level within the fair value hierarchy (in thousands):

	As of June 30, 2023	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	As of September 30, 2023	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets								
Cash equivalents:								
Money market funds	$ 22,700	$ 22,700	$ —	$ —	$ 51,061	$ 51,061	$ —	$ —

U.S. treasury securities	6,616	—	6,616	—	18,944	—	18,944	—
Marketable securities								
U.S. treasury securities	33,796	—	33,796	—	34,252	—	34,252	—
Corporate debt securities	52,648	—	52,648	—	41,404	—	41,404	—
Total assets	$ 115,760	$ 22,700	$ 93,060	$ —	$ 145,661	$ 51,061	$ 94,600	$ —

	As of December 31, 2022	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash equivalents:				
Money market funds	$ 55,861	$ 55,861	$ —	$ —
Marketable securities				
U.S. treasury securities	22,606	—	22,606	—
Corporate debt securities	74,422	—	74,422	—
Total assets	$ 152,889	$ 55,861	$ 97,028	$ —

During the six nine months ended June 30, 2023 September 30, 2023 and year ended December 31, 2022, there were no transfers into or out of Level 3.

4. Marketable securities

The following table summarizes tables summarize the Company's marketable securities (in thousands):

	As of June 30, 2023				As of September 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 40,430	$ 2	$ (20)	$ 40,412	$ 53,198	$ 2	$ (4)	$ 53,196
Corporate debt securities	53,086	—	(438)	52,648	41,692	—	(288)	41,404
Total	$ 93,516	$ 2	$ (458)	$ 93,060	$ 94,890	$ 2	$ (292)	$ 94,600

	December 31, 2022				As of December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 22,630	$ —	$ (24)	$ 22,606	$ 22,630	$ —	$ (24)	$ 22,606
Corporate debt securities	75,161	—	(739)	74,422	75,161	—	(739)	74,422
Total	$ 97,791	$ —	$ (763)	$ 97,028	$ 97,791	$ —	$ (763)	$ 97,028

	As of September 30, 2023					
	Less than 12 Months		12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	$ (10)	$ 29,273	$ -	$ -	$ (10)	$ 29,273
Corporate debt securities	(166)	28,269	(116)	13,135	(282)	41,404
Total	$ (176)	$ 57,542	$ (116)	$ 13,135	$ (292)	$ 70,677

In accordance with the Company's investment policy, it places investments in investment grade securities with high credit quality issuers, and generally limits the amount of credit exposure to any one issuer. The Company evaluates securities for impairment at the end of each reporting period. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the issuer, and the Company's intent and ability to hold the investment to allow for an anticipated recovery in fair value.

As of June 30, 2023 September 30, 2023, the Company held 34 28 marketable securities in an unrealized loss position. The Company does not intend to sell its marketable securities and it is not more likely than not that the Company will be required to sell the investments before the recovery of their amortized cost bases, which may be maturity. The Company also believes that it will be able to collect both principal and interest amounts due at maturity. The Company did not record any impairment charges related to its available-for-sale securities during the three and six nine months ended June 30, 2023 September 30, 2023 and 2022. The Company did not recognize any credit-related allowance to available-for-sale securities as of the three and six nine months ended June 30, 2023 September 30, 2023 and 2022.

The fair values of the Company's marketable securities by classification in the condensed consolidated balance sheets were as follows:

	As of June 30, 2023	As of December 31, 2022	As of September 30, 2023	As of December 31, 2022
Cash and cash equivalents	$ 6,616	$ —	$ 18,944	$ —
Marketable securities	86,444	97,028	75,656	97,028
Total	$ 93,060	$ 97,028	$ 94,600	$ 97,028

Marketable securities fair value by contractual maturity were as follows (in thousands):

	As of June 30, 2023	As of December 31, 2022	As of September 30, 2023	As of December 31, 2022
Due in one year or less	$ 85,071	$ 79,652	$ 89,278	$ 79,652
Due after one year through five years	7,989	17,376	5,322	17,376
Total	$ 93,060	$ 97,028	$ 94,600	$ 97,028

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	As of June 30, 2023	As of December 31, 2022	As of September 30, 2023	As of December 31, 2022
Clinical, manufacturing and scientific development	$ 1,025	$ 1,372	$ 1,621	$ 1,372
Prepaid Insurance	1,578	727	1,061	727
Other	731	964	1,019	964
Total	$ 3,334	$ 3,063	$ 3,701	$ 3,063

6. Property and Equipment, net

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

	As of June 30, 2023	As of December 31, 2022	As of September 30, 2023	As of December 31, 2022
Property and equipment:				
Lab equipment	$ 2,980	$ 2,858	$ 2,980	$ 2,858
Leasehold improvements	1,219	1,216	1,219	1,216

Electronic equipment and software	480	481	481	481
Furniture and fixtures	475	475	475	475
Total property and equipment	5,154	5,030	5,155	5,030
Less: accumulated depreciation	(2,279)	(1,825)	(2,522)	(1,825)
Property and equipment, net	$ 2,875	$ 3,205	$ 2,633	$ 3,205

Depreciation expense for the three months ended June 30, 2023 September 30, 2023 and 2022 was $0.2 million and $0.3 0.2 million, respectively. Depreciation expense for the six nine months ended June 30, 2023 September 30, 2023 and 2022 was $0.5 0.7 million and $0.5 0.7 million, respectively. There were no impairments for the six nine months ended June 30, 2023 September 30, 2023 and 2022.

7. Accrued Expenses and Other Current Liabilities

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

	As of June 30, 2023	As of December 31, 2022	As of September 30, 2023	As of December 31, 2022
Employee compensation	$ 1,929	$ 3,236	$ 2,961	$ 3,236
Research and development expenses	3,436	4,462	6,140	4,462
Professional fees	1,080	526	1,633	526
Other current liabilities	10	119	459	119
Total	$ 6,455	$ 8,343	$ 11,193	$ 8,343

8. Collaboration Agreement and Stock Purchase Agreement with Bristol-Myers Squibb

In January 2019, the Company entered into the Bristol-Myers Squibb Collaboration Agreement with Celgene Corporation, which was acquired by Bristol-Myers Squibb in November 2019, whereby the Company will carry out initial research and development activities with the goal of identifying and developing drug candidates for certain cancer types. Concurrent with execution of the Bristol-Myers Squibb Collaboration Agreement, the Company entered into a stock purchase agreement with Bristol-Myers Squibb, which resulted in the issuance of 14,545,450 shares of Series A-1 Preferred Stock (the "Stock Purchase Agreement"). In connection with the Company's initial public offering ("IPO"), the series A-1 preferred stock converted into common stock.

Agreement Structure

Under the Bristol-Myers Squibb Collaboration Agreement, the Company will conduct exploratory and discovery activities, with the goal of identifying product candidates for certain targets, which are in the kynurenine pathway, which the Company is developing as IK-412, and the AHR pathway, which the Company is developing as IK-175. The Company is obligated to advance research and

development activities through the earlier of January 2024 or the completion of a Phase 1b clinical trial for each program ("the research term"). Bristol-Myers Squibb has the option to receive a global-development, manufacture and commercialization license for the product candidate, which expires in January 2024. Subsequent to the delivery of a license, Bristol-Myers Squibb is responsible for the worldwide development, manufacturing and commercialization of these product candidates.

Bristol-Myers Squibb paid the Company a total of $95.0 million in aggregate upfront consideration related to the Bristol-Myers Squibb Collaboration Agreement and Stock Purchase Agreement. The Company is eligible to receive $50.0 million, in case of an exercise of its option with respect to IK-175, and $40.0 million, in case of an exercise of its option with respect to IK-412. If the Company does not complete a Phase 1b clinical trial by the end of the research term, the Company may provide a data package to Bristol-Myers Squibb to support the decision to exercise the option for an additional $0.25 million. Upon the exercise of the delivery of each license, the Company becomes eligible to receive up to $450 million in milestone payments, as well as a tiered royalty on worldwide sales from the high single to low teen digits.

Accounting Considerations of the Agreement

The Bristol-Myers Squibb Collaboration Agreement and the Stock Purchase Agreement were executed concurrently and in contemplation of each other. The issuance of Series A-1 Preferred Stock was initially accounted for at fair value. The purchase price for the Series A-1 Preferred Stock was considered to be at a discount from fair value, and therefore $1.8 million of the upfront from the Bristol-Myers Squibb Collaboration Agreement was allocated to the equity arrangement.

The Company determined that the Bristol-Myers Squibb Collaboration Agreement represented a contract with a customer and should be accounted for in accordance with ASC 606. The Company identified the two performance obligations, which are research and development services for IK-175 and IK-412. The options to receive worldwide development and commercialization licenses for the two targets and the option to receive manufacturing services in the future were determined to not provide any material rights to the customer and are therefore not considered to be performance obligations. The arrangement also contains certain other items, including participation on joint oversight committees.

The Company identified $78.7 million of total transaction price which represents the upfront consideration allocated to the revenue arrangement. Additional consideration to be paid to the Company upon exercise of a right to receive a license or potential milestone and royalty payments are excluded from the transaction price as they relate to amounts that can only be achieved subsequent to the exercise of an option and are outside of the initial contact term.

Based on the distinct performance obligations identified above, the Company allocated the $78.7 million transaction price based on relative estimated standalone selling prices of each of its performance obligations as follows:

- $41.2 million for research and development services for IK-175; and
- $37.5 million for research and development services for IK-412.

The Company determined the estimated standalone selling price for the research and development services based on internal estimates of the costs to perform the services, including expected internal expenses and expenses with third parties, adjusted to include a reasonable profit margin. Significant inputs used to determine the total expense of the research and development activities include the length of time required and the number and cost of various studies that will be performed to complete the applicable development plan.

The Company is recognizing revenue related to each of its performance obligations as the research and development services are performed through January 2024. The Company recognizes revenue related to research and development services performed using an input method by calculating costs incurred at each period end relative to total costs expected to be incurred.

In December 2021, the Company re-assessed the IK-412 program, which experienced manufacturing delays as a key component required in the manufacturing of IK-412, is similarly essential to the manufacturing of COVID-19 vaccines and therapies. As such, the availability of the component was delayed as resources were allocated towards vaccine production. Considering these delays and the timeline of the Bristol-Myers Squibb partnership, the Company made the strategic decision to pause IK-412 development activities for the remainder of the Bristol-Myers Squibb research term outside of the committed manufacturing efforts, which were completed in 2022.

The Company recognized revenue of $2.0 1.2 million and $0.4 6.4 million in the three months ended June 30, 2023 September 30, 2023 and 2022 and $7.3 8.5 million and $3.8 10.2 million six nine months ended June 30, 2023 September 30, 2023 and 2022 respectively, from the Bristol-Myers Squibb Collaboration Agreement, that in each case was previously included in deferred revenue at the beginning of the respective period. The condensed consolidated balance sheet as of June 30, 2023 September 30, 2023 includes current deferred revenue of $1.8 0.7 million related to this agreement. This

amount is expected to be recognized as performance obligations are satisfied through the completion of the research and development services for the partnered programs.

9. Acquisition of Pionyr Therapeutics

On August 4, 2023, the Company acquired Pionyr, pursuant to the Pionyr Acquisition Agreement. Under the terms of the Pionyr Acquisition Agreement, the Company issued to the stockholders of Pionyr 1,800,652 shares of the Company's common stock (including 153,121 shares of the Company's non-voting common stock), and 4,153,439 shares of Series A Preferred Stock, which was a newly designated series of preferred stock that is intended to have economic rights equivalent to the Company's common stock, but with only limited voting rights. The Series A Preferred Stock converted to shares of the Company's common stock pursuant to stockholder approval at a special meeting of stockholders held on October 11, 2023. See "Note 15 – Subsequent Event" for additional information on stockholder approval of the conversion. Each stockholder of Pionyr at the time of closing also received one contractual

CVR for each share of Pionyr stock held at closing. The CVR entitles the holder to receive 50% of net proceeds, outside of royalties, for any potential monetization of Pionyr legacy programs within two years.

Acquisition Accounting

The Company concluded that the Acquisition should be accounted for as a capitalization transaction, primarily based on the following facts and circumstances:

- The purpose of the transaction was for the Company to acquire the cash, cash equivalents and marketable securi of Pionyr;
- A nominal amount of Pionyr's others assets were acquired, primarily related to the right-of-use-asset for Pionyr's office and lab space lease located in San Francisco, California. The Company is actively seeking a tenant to subleas the space;
- Prior to the Acquisition, Pionyr was finalizing the wind down of all development activities that were ongoing. Ther will be no continuing operations of Pionyr other than the remaining wind down activities;
- No value has been ascribed to the legacy intellectual property assets acquired; and
- No assembled workforce or substantive processes were acquired that together could significantly contribute to t ability to create outputs.

Under the recapitalization accounting model, the assets acquired and liabilities assumed were recognized at their fair value on August 4, 2023. The equity issued by the Company was recognized on the basis of the net fair value of the assets acquired and liabilities assumed. Cash consideration transferred and transaction costs incurred attributable to the Acquisition are reflected as reductions to equity. The Company incurred $1.4 million of transaction costs that were direct and incremental to the Acquisition.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the Acquisition date (in thousands):

Assets Acquired	**As of August 4, 2023**
Cash and cash equivalents	$ 40,926

Marketable securities		20,362
Prepaid expenses and other current assets		1,359
Right-of-use-asset		3,889
Deposits and other assets		406
Total assets acquired	$	66,942
Liabilities Assumed		
Accounts payable		(2,844)
Accrued expenses and other current liabilities		(8,097)
Operating lease liability		(1,485)
Long-term portion of operating lease liability		(5,647)
Other long term liabilities		(852)
Total liabilities assumed	$	(18,925)
Net assets acquired (1)	$	48,017

(1) Net assets acquired does not include the remaining costs to complete the wind down of Pionyr development activities and operations.

Fair value of equity issued and consideration transferred in connection with the Acquisition (in thousands):

	As of August 4, 2023	
Issuance of Series A Preferred Stock	$	32,837
Issuance of common stock		14,236
Cash consideration paid to settle Pionyr restricted stock units ("RSUs") and stock options		738
Cash consideration paid to Pionyr unaccredited stockholders		206
Total	$	48,017

The CVR was not accounted for as a derivative on the date of merger, nor was it included in the consideration transferred to acquire Pionyr. As of August 4, 2023 and September 30, 2023, the contingent consideration cannot be reasonably estimated, and the contingency was not resolved.

10. Stockholder's Equity

Common Stock

On May 17, 2023, we the Company completed an underwritten registered offering ("URO") of common stock pursuant to which we it issued and sold 6,110,000 shares of our the Company's common stock at a purchase price of $6.55 per share. We The Company received net proceeds from the URO of approximately $37.4 million after deducting

commissions and other offering expenses. The URO was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-264517).

On August 4, 2023, the Company acquired 100% of the outstanding equity of Pionyr. Pursuant to the Acquisition, the Company issued to Pionyr stockholders 1,800,652 shares of the Company's common stock (including 153,121 shares of the Company's non-voting common stock). The Company also issued 4,153,439 shares of common stock issuable upon the conversion of 4,153,439 shares of Series A Preferred Stock to Pionyr stockholders pursuant to the Acquisition.

Preferred Stock

On August 4, 2023, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock ("Certificate of Designation") with the Secretary of State of the State of Delaware in connection with the Acquisition, which provides for the issuance of shares of Series A Preferred Stock. Pursuant to the Acquisition, the Company agreed to issue 4,153,439 shares of Series A Preferred Stock to Pionyr stockholders. The Company agreed to hold a special meeting of stockholders to submit the approval of the conversion of the Series A Preferred Stock into shares of common stock, pursuant to which each share of Series A Preferred Stock would be convertible into one share of voting common stock, provided, however, that if such stockholder already held shares of the Company's non-voting common stock prior to the conversion, such holder would receive shares of non-voting common stock in lieu of shares of voting common stock to the extent the issuance of shares of voting common stock to such holder would result in such holder, when aggregated with its affiliates for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), beneficially owning more than 9.99% of the Company's voting common stock (the "Non-Voting Beneficial Ownership Limitation"). If stockholders had not approved the conversion of the Series A Preferred Stock into common stock by February 4, 2024 (six (6) months from the closing of the Acquisition), then, upon any attempted conversion, holders of Series A Preferred Stock may have thereafter required the Company to repurchase the Series A Preferred Stock at the then-current fair value of the underlying Common Stock.

On September 25, 2023, the Company filed a Definitive Proxy Statement with the SEC to solicit approval of the issuance of common stock upon conversion of the Series A Preferred Stock at a special meeting of stockholders.

The Company classified convertible preferred stock as temporary equity in the accompanying consolidated statement of Convertible Preferred Stock and Stockholders' Equity due to terms that allow for redemption of the shares in cash upon certain events that are outside of the Company's control, including failure to obtain stockholder approval of the conversion of the Series A Preferred Stock. The Company did not accrete the value of the convertible preferred stock to the redemption values since a liquidation event was not considered probable prior to the conversion date. As of September 30, 2023, the redemption value of the Company's outstanding Series A Preferred Stock was $18.0 million based on the closing stock price of the Company's common stock on September 30, 2023 of $4.33 per share.

The Series A Preferred Stock was subsequently converted to shares of the Company's common stock pursuant to stockholder approval at a special meeting of stockholders held on October 11, 2023. See "Note 15 – Subsequent Event" for additional information on stockholder approval of the conversion.

Voting Rights

Except as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock, (b) alter or amend the Certificate of Designation, (c) amend or repeal any provision of, or add any provision to, our certificate of incorporation or bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of, the Series A Preferred Stock, (d) issue further shares of Series A Preferred Stock

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or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock, (e) prior to the stockholder approval of the conversion of the Series A Preferred Stock into shares of common stock or at any time while at least 30% of the originally issued Series A Preferred Stock remains issued and outstanding, consummate a Fundamental Transaction (as defined in the Certificate of Designation) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, (f) authorize or issue any class or series of stock that has powers, preferences or rights that are senior to those of the Series A Preferred Stock, or (g) enter into any agreement with respect to any of the foregoing.

Dividends

Holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock equal, on an as-if-converted-to-common-stock basis and without regard to the Non-Voting Beneficial Ownership Limitation, equal to and in the same form as dividends actually paid on shares of common stock.

Liquidation and Dissolution.

The Series A Preferred Stock ranks (i) senior to any class or series of capital stock of the Company created after the date of the Acquisition specifically ranking by its terms junior to any Series A Preferred Stock and (ii) on parity with common stock upon any liquidation, dissolution or winding-up of the Company.

Equity Incentive Plan

The Company grants stock options under the 2021 Stock Incentive Plan (the "2021 Plan"). The Company also has stock options outstanding under the 2016 Stock Incentive Plan ("2016 Plan"), but is no longer granting awards under such plan. All shares of common stock underlying any awards that are forfeited, cancelled, expired, repurchased, or otherwise terminated under the 2021 and 2016 Plans are added back to the shares of common stock available for issuance under the 2021 Plan. On January 1, 2023, the number of shares available for issuance under the 2021 Plan increased by 1,450,299

shares as a result of the evergreen provision. As of June 30, 2023 September 30, 2023, 3,091,538 3,264,419 shares of common stock remain available for future issuance under the 2021 Plan.

The total compensation expense recognized in the statements of operations associated with all the stock-based compensation awards granted by the Company is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
Research and development	$ 984	$ 1,069	$ 2,056	$ 2,066	$ 1,058	$ 865	$ 3,114	$ 2,931
General and administrative	895	886	1,823	1,789	940	946	2,763	2,735
Total	$ 1,879	$ 1,955	$ 3,879	$ 3,855	$ 1,998	$ 1,811	$ 5,877	$ 5,666

The weighted-average fair value of the stock options granted during the six nine months ended June 30, 2023 September 30, 2023 was $2.23 2.25. As of June 30, 2023 September 30, 2023, the total unrecognized stock-based compensation expense for unvested options was $15.9 13.4 million which is expected to be recognized over a weighted average period of 2.5 2.3 years.

The following table summarizes stock option activity under the 2021 Plan for the six nine months ended June 30, 2023 September 30, 2023:

Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)

Outstanding as of December 31, 2022	6,589,479	$	7.29	7.73	$	362	6,589,479	$	7.29	7.73	$	362
Granted	1,561,115		3.00				1,597,224		3.02			
Exercised	(29,485)		4.11				(34,027)		4.01			
Cancelled or forfeited	(562,439)		6.18				(735,320)		6.44			
Outstanding as of June 30, 2023	7,558,670	$	6.50	7.72	$	12,170						
Vested or expected to vest as of June 30, 2023	7,558,670	$	6.50	7.72	$	12,170						
Options exercisable as of June 30, 2023	3,695,490	$	6.45	6.62	$	5,915						
Outstanding as of September 30, 2023							7,417,356	$	6.47	7.13	$	4,062
Vested or expected to vest as of September 30, 2023							7,417,356	$	6.47	7.13	$	4,062
Options exercisable as of September 30, 2023							3,920,894	$	6.58	6.22	$	1,733

The aggregate intrinsic value of options exercised for the six nine months ended June 30, 2023 September 30, 2023 and 2022 was $0.1 59.3 million thousand and $1.2 million, respectively.

The fair value of each option award granted is estimated on the date of grant using the Black-Scholes option pricing model and the weighted average assumptions. The underlying assumptions used to value stock options granted to participants using the Black-Scholes option-pricing presented on a weight average basis were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
Risk-free interest rate	3.8 9 %	1.6 7 %	3.9 1 %	2.2 3 %	4.73 %	2.89 %	3.91 %	2.36 %
Expected dividend yield	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
Expected option term (in years) range	5.71	6.07	6.03	5.99				
Expected option term (in years)					6.08	6.08	6.03	6.01
Expected stock price volatility	87. 23 %	83. 55 %	86. 55 %	84. 41 %	90.9 2 %	85.7 6 %	86.5 5 %	84.6 8 %

Employee Stock Purchase Plan

On March 20, 2021, the Company's stockholders approved the 2021 Employee Stock Purchase Plan (the "ESPP"), which became effective on March 30, 2021. The ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 346,613 shares of the Company's common stock. An annual increase in the number of shares of common stock reserved and available for issuance under the ESPP shall be equal to 1% of the number of shares of common stock outstanding on the immediately preceding December 31; and such lesser number of shares as determined by the Administrator as provided in the ESPP. As of June 30, 2023 September 30, 2023, there has been no increase in the shares reserved and available for issuance and no shares have been purchased by employees under the ESPP.

10. 11. Research License Agreements

During 2015, the Company entered into an exclusive patent license agreement (the "UT Austin License") to license certain technologies and intellectual property rights from the University of Texas at Austin (the "University"), an entity affiliated with a director of the Company at the time of the agreement. The UT Austin License shall remain in effect until the expiration or abandonment of the last to expire technologies and intellectual property rights. The Company shall pay License Maintenance fees annually of $40 thousand. Additionally, the Company shall make additional milestone payments to the University upon meeting certain development milestones in the aggregate of $4.7 million upon meeting certain development milestones during the term of the UT Austin License. The Company will pay the University royalties as defined in the UT Austin License on any commercialized product sales related to the licensed technology in a percentage in the low single digits. The Company will also be responsible for reimbursing the University for certain patent-related costs incurred on its behalf.

In 2018, the Company acquired IPR&D on an Arrys' immune-oncology candidate based on the intellectual property associated with Arrys' AskAt License as part of the acquisition of Arrys. Total consideration allocated to the technology was $28.5 million and was recognized as research and development expense upon the acquisition. The AskAt License is was intended to be used by the Company in its future development of therapeutic drug candidates for eventual clinical development and commercialization. The Company shall make additional milestone payments agreement will be terminated as of March 2024 and all assets will be returned to AskAt upon meeting certain development milestones totaling $4 million, Inc. as well as certain sales event milestones ranging from $50 million to $250 million contingent on sales in a calendar year, during of March 2024, at which point no further costs will be incurred by the term of the AskAt License. The Company will pay the AskAt royalties a percentage in the low single digits as defined in the AskAt License on any commercialized product sales related to the licensed technology. Company.

11. 12. Commitments and Contingencies

The Company is also party to various agreements, principally relating to licensed technology, that require future payments relating to milestones not met as of June 30, 2023 September 30, 2023 or royalties on future sales of specified products that have not yet occurred as of June 30, 2023 September 30, 2023.

12. 13. Net Loss per Share Attributable to Common Stockholders

The Company has generated a net loss in all periods presented, therefore the basic and diluted net loss per share attributable to common stockholders are the same as the inclusion of the potentially dilutive securities would be anti-dilutive.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive:

	Six Months Ended June 30,	
	2023	2022
Options to purchase Common Stock	7,558,670	6,581,026
Total	7,558,670	6,581,026

	Nine Months Ended September 30,	
	2023	2022
Options to purchase Common Stock	7,417,356	6,701,407
Convertible Preferred Stock	4,153,439	—
Total	11,570,795	6,701,407

13. Subsequent Event 14. Related Party Transactions

On August 4, 2023, the Company acquired Pionyr Immunotherapeutics, Inc., OrbiMed Advisors LLC ("Pionyr" OrbiMed"), a privately-held company headquartered in San Francisco, California, in accordance related party of the Company, was previously a stockholder of Pionyr. In connection with the terms of the Agreement and Plan of Merger, dated August 4, 2023 (the "Merger Agreement"). Under the terms of the Merger Agreement, at the closing of the Merger, the Company acquired all of Pionyr's assets, including approximately $ Acquisition, OrbiMed was allocated 43 million in net cash at the time of closing, and the Company issued the holders of Pionyr common stock a total of 1,800,652 153,121 shares of the Company's common stock, comprised of both voting and non-voting common stock at the purchase price of $7.15 per share and 4,153,439 353,192 shares of Series A Preferred Stock, (as defined which converted to common stock pursuant to stockholder approval at a special meeting of stockholders held on October 11, 2023. As of September 30, 2023, OrbiMed beneficially owned approximately 8.9% of the Company's voting common stock outstanding.

15. Subsequent Event

On September 25, 2023, the Company filed a Definitive Proxy Statement which included the proposal that the Company's stockholders approve the conversion of the shares of Series A Preferred Stock issued in the Merger Agreement), also at the purchase price of $7.15 per share, each share of which is convertible Acquisition into one (1) share shares of the Company's common stock, subject stock. The proposal was approved by the stockholders at a special meeting of stockholders held on October 11, 2023. Pursuant to certain conditions. The Company is in process the Certificate of evaluating Designation, the accounting treatment conversion was effective as of the transaction.October 16, 2023 at 5:00 p.m. Eastern Time.

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 condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K that was filed with the Securities and Exchange Commission ("SEC") on March 14, 2023. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q includes forward-looking statements that involve risks and uncertainties, such as statements of our plans, strategies, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section 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.

Overview

We are a targeted oncology company, focused on developing differentiated therapies for patients in need that target nodes of cancer growth, spread, and therapeutic resistance in the Hippo and RAS onco-signaling network. Our lead targeted oncology program, IK-930, is a TEAD1-selective Hippo pathway inhibitor, a known tumor suppressor pathway that also drives resistance to multiple targeted therapies. Our first program in the RAS pathways, pathway, IK-595, is a molecular glue designed to trap MEK and RAF in an inactive complex, more completely inhibiting RAS signals than existing inhibitors. We have a robust discovery engine and a portfolio of early stage targeted oncology programs that are designed to complement our current pipeline and follow our patient-driven target selection strategy. Our depth of institutional knowledge and ability to create bespoke processes and programs enable us to efficiently develop the right drug using the right modality for the right patient. In addition to our targeted oncology programs we are developing IK-175, an aryl hydrocarbon receptor ("AHR") antagonist in collaboration with Bristol-Myers Squibb Company ("Bristol-Myers Squibb"), a program also grown from internal discovery. Since we commenced operations in 2016, we have advanced multiple product candidates into clinical development.

Our most advanced targeted oncology product candidate, IK-930, is an oral, TEAD1-selective, small molecule inhibitor of the Hippo signaling pathway. The Hippo pathway is a key driver of cancer pathogenesis that is genetically altered in approximately 10% of all cancer types and plays a role in resistance to other targeted therapies. IK-930 selectively binds to TEAD1 and prevents transcription of multiple genes that drive cancer progression. Our ongoing Phase 1 clinical trial is currently evaluating IK-930 as monotherapy in patients with advanced solid tumors with or without gene alterations in the Hippo pathway. The trial includes plans for expansion cohorts in targeted patient populations, including in patients with mesothelioma and EHE. epithelioid hemangioendothelioma ("EHE"). Approximately 40% of mesothelioma patients are genetically deficient for the tumor suppressor NF2 and 100% of EHE patients have oncogenic YAP1 or TAZ gene fusions. The first patient in the clinical trial was dosed in January 2022, and since IK-930 has received orphan designation for the treatment of mesothelioma and fast track designation for unresectable NF2-deficient mesothelioma from the U.S. Food and Drug Administration ("FDA"). Initial IK-930 has shown a differentiated safety profile in dose escalation and early signs of

clinical activity in EHE. Additional clinical data from the dose escalation is expected in the fourth quarter second half of 2023.2024.

In addition to the monotherapy approach, we plan to assess IK-930 in combination with other targeted therapies across several indications with multiple targeted therapies to combat therapeutic resistance. Based on the role that the Hippo pathway plays in resistance to other targeted therapies, we believe that IK-930 may expand the patient populations that could benefit from targeted therapies like epidermal growth factor receptor ("EGFR") inhibitors, KRAS inhibitors, and MEK inhibitors, among others. Our preclinical data highlight the potential of IK-930 in combination with osimertinib in EGFR mutant cancers, both in first line as a resistance-preventative combination and in later lines, post-resistance emergence. We have an established clinical collaboration with AstraZeneca for the evaluation of osimertinib in combination with IK-930 for patients with EGFR-mutant non-small cell lung cancers as a cohort in the ongoing Phase 1 clinical trial.trial, which is planned to initiate in 2024.

In addition to our work in the Hippo pathway, we are developing targeted therapies within the RAS pathway, one of the most highly dysregulated pathways in cancer. The RAS pathway is implicated in at least half a million new cancer diagnoses each year in the United States alone. Our goal is to achieve deep and sustained responses through targeting the pathway on multiple levels and leveraging the biology of known resistance mechanisms in our therapeutic design. Our first program in the space, IK-595, is aims for robust inhibition of MEK-RAF by trapping gluing MEK and RAF in an inactive complex, more completely inhibiting RAS signals than existing inhibitors. IK-595's potential ability to complex CRAF, in particular, prevents a well-recognized signaling bypass mechanism that cancer cells employ to drive therapeutic resistance to other drugs in this class. In addition, trapping CRAF in an inactive complex prevents the kinase independent anti-apoptotic function in RAS and RAF mutant cancers, a mechanism that cannot be addressed with first generation MEK inhibitors or pan-RAF inhibitors. We are developing IK-595 as an oral therapy, with a half-life designed to enable a pharmacokinetic profile that we believe can be potentially superior to other pathway inhibitors, with the goal of optimizing the therapeutic window for patients. We plan are anticipating clinical trial activities for a Phase I IK-595 clinical program to submit an Investigational New Drug Application ("IND") to the FDA for IK-595 initiate in the second half fourth quarter of 2023.

Our pipeline also includes our Bristol Myers Squibb partnered immune-signaling program targeting AHR with our novel inhibitor, IK-175. The Phase 1a/1b clinical trial was designed to evaluate IK-175 as a monotherapy and in combination with nivolumab in patients with advanced or metastatic solid tumors, including urothelial carcinomas, for which current standard-of-care therapy is no longer effective or is intolerable. Initial clinical data from the program was presented in November 2022 at the Society for Immunotherapy of Cancer Annual Meeting. These initial data included a 40% disease control rate and 20% overall response rate in urothelial carcinoma patients who received IK-175 in combination with nivolumab, with the majority of combination patients experiencing reduction in their target lesions. In March 2023, the FDA granted fast track designation for IK-175 in combination with immune checkpoint inhibitors in patients with advanced

urothelial carcinoma who have progressed on or within three months of receiving the last dose of checkpoint inhibitors. Enrollment has been completed and the program is eligible for opt-in from Bristol Myers Squibb through early 2024. In addition to IK-175, we hold rights to several programs that are considered part of our strategic partnering portfolio, including the programs acquired from Pionyr Immunotherapeutics, Inc. ("Pionyr") in August 2023.

All of our ongoing development programs stemmed from our internal discovery engine, which continues its focus on discovering and developing novel targeted oncology programs. Our early research follows our philosophy of designing treatments for selected patient populations. Our approach in each of our programs is to target cancer-driving targets that can also be implicated in mechanisms of therapeutic resistance, bringing the potential to expand the patient population that can benefit from targeted oncology.

On May 17, 2023, we completed an underwritten registered offering ("URO") of common stock pursuant to which we issued and sold 6,110,000 shares of our common stock at a purchase price of $6.55 per share. We received net proceeds of approximately $36.4 million after deducting commissions and other offering expenses. The URO was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-264517).

On August 4, 2023, we acquired Pionyr, in accordance with the terms of the Agreement and Plan of Merger, dated August 4, 2023 (the "Merger Agreement"). Under the terms of the Merger Agreement, at the closing of the Merger, Acquisition, we acquired all of Pionyr's assets, including approximately $43 million in net cash at the time of closing, and we issued the holders of Pionyr common stock a total of 1,800,652 shares of the Company's common stock (including 153,121 shares of our non-voting common stock) at the purchase price of $7.15 per share and 4,153,439 shares of Series A Preferred Stock (as defined in the Merger Agreement), also at the purchase price of $7.15 per share, each share of which is convertible into one (1) share of the Company's common stock, subject to certain conditions. On September 25, 2023, we filed a Definitive Proxy Statement which included the proposal that our stockholders approve the conversion of the shares of Series A Preferred Stock issued in the Acquisition into shares of the Company's common stock. The proposal was approved by the stockholders at a special meeting of stockholders held on October 11, 2023.

To date, we have not had any products approved for sale and have not generated any revenue from product sales.

Financial Operations

To date, we have primarily financed our operations through proceeds from private placements of preferred stock, payments from a collaboration agreement, related party revenue, and the completion of our initial public offering ("IPO"), underwritten registered offering of common stock ("URO"), and URO. acquisition of Pionyr.

Since inception, we have incurred significant operating losses. Our net losses were $31.3 million $48.7 million and $37.3 million $54.7 million for the six nine months ended June 30, 2023 September 30, 2023 and 2022, respectively. As of June 30, 2023 September 30, 2023, we had an accumulated deficit of $245.6 million $262.9 million. We expect to continue to incur significant expenses and operating losses, which could be substantial, for at least the next several years as we:

- advance the development of our product candidate pipeline;
- initiate and continue research and preclinical and clinical development of potential new product candidates;

- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license additional product candidates and technologies;
- expand our infrastructure and facilities to accommodate our growing employee base and ongoing development activities;
- continue to establish agreements with clinical research organizations ("CROs") and contract manufacturing organizations ("CMOs") in connection with our preclinical studies and clinical trials;
- require the manufacture of larger quantities of our product candidates for clinical development and potential commercialization;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obta marketing approval; and
- add operational, financial and management information systems and personnel, including personnel, to support research and development programs, any future commercialization efforts, and our continued operations as a pu company.

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

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

As of June 30, 2023 September 30, 2023, we had cash, cash equivalents, and marketable securities of $157.3 million $196.9 million. We believe the existing cash, cash equivalents, and marketable securities as of June 30, 2023 September 30, 2023 will enable us to fund our operating expenses and capital expenditure requirements into 2026. To

date, we have primarily financed our operations through proceeds from private placements of preferred stock, payments from a collaboration agreement, related party revenue, and completion of the IPO and URO. URO, and the acquisition of Pionyr. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future as we continue to invest significantly in research and development of our programs. Our belief with respect to our ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from our estimates, we may need to seek additional funding sooner that than would otherwise be expected. There can be no assurance that we will be able to obtain additional funding on acceptable terms, if at all.

Components of our Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval and successful commercialization efforts, we may generate revenue in the future from product sales. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

All of our revenue has been derived from research and development revenue under our Bristol-Myers Squibb Collaboration Agreement.

Collaboration Agreement and Stock Purchase Agreement with Bristol-Myers Squibb

In January 2019, we entered into the Bristol-Myers Squibb Company Collaboration Agreement with Celgene Corporation (which was acquired by Bristol-Myers Squibb in November 2019), pursuant to which Bristol-Myers Squibb may elect in its sole discretion to exclusively license rights to develop and commercialize compounds (and products and diagnostic products containing such compounds) that modulate the activity of two collaboration targets, kynurenine and AHR, excluding AHR agonists for inverse agonists, which we are developing as IK-412 and IK-175, respectively. On a program-by-program basis, through the earlier of January 2024 or the completion of a Phase 1b clinical trial for each of IK-175 and IK-412, Bristol-Myers Squibb has the exclusive option to exclusively license to develop, commercialize and manufacture the relevant product candidate worldwide. Concurrent with execution of the Bristol-Myers Squibb Collaboration Agreement, we entered into a stock purchase agreement with Celgene Corporation (now Bristol-Myers Squibb) in November 2019 (“Stock Purchase Agreement”), pursuant to which we issued Celgene Corporation 14,545,450 shares of Series A-1 preferred stock.

Bristol-Myers Squibb paid a total of $95.0 million in aggregate upfront consideration related to the Bristol-Myers Squibb Collaboration Agreement and Stock Purchase Agreement. We are eligible to receive $50.0 million, in case of an exercise of its option with respect to IK-175, and $40.0 million, in case of an exercise of its option with respect to IK-412. If we do not complete a Phase 1b clinical trial by the end of the research term, we may elect to provide a data package to Bristol-Myers Squibb upon which Bristol-Myers Squibb may exercise the foregoing option for an additional $0.25 million fee. Development of IK-412 was paused in 2021, outside of the committed manufacturing efforts, in part due to COVID-19

related delays. Bristol-Myers Squibb retains the option to license IK-412 according to the terms of the Bristol-Myers Squibb Collaboration Agreement. Upon the exercise of the delivery of each

18

license, we become eligible to receive up to $265.0 million in regulatory milestones and $185.0 million in commercial milestones as

15

well as a tiered royalties at rates ranging from the high single to low teen digits percentages based on worldwide annual net sales by Bristol-Myers Squibb, subject to specified gross sale reductions.

Operating Expenses

Our operating expenses since inception consist solely of research and development costs and general and administrative costs.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research and development activities. These efforts and costs include external research costs, personnel costs, consultants, supplies, license fees and facility-related expenses. We expense research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred under agreements with CROs, which are primarily engaged to support our clinical trials;
- expenses incurred under agreements with CMOs, which are primarily engaged to provide drug substance and product for our preclinical research and development programs, nonclinical studies and other scientific developm services;
- the cost of acquiring and manufacturing preclinical study materials, including manufacturing registration and validation batches;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance facilities and insurance;
- acquisition of in-process research and development assets that have no alternative future use;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are

delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of, or obtain regulatory approval for, any of our current or future product candidates. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- our ability to add and retain key research and development personnel;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our produ candidates;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from a such trials;
- the size and cost of any future clinical trials for existing or future product candidates in our pipeline;
- the costs associated with the development of any additional programs we identify in-house or acquire through collaborations and other arrangements and the success of such collaborations;
- the terms and timing of any additional collaborations, license or other arrangement, including the timing of any payments thereunder;
- our ability to establish and maintain agreements and operate with third-party manufacturers for clinical supply fo our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- costs related to manufacturing of our product candidates or to account for any future changes in our manufactur plans;

- our ability to obtain and maintain patents, trade secret, and other intellectual property protection and regulatory exclusivity for our product candidates, both in the United States and internationally;
- our ability to obtain and maintain third-party insurance coverage and adequate reimbursement for our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community and third-party payo
- effectively competing with other products if our product candidates are approved;
- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic pandemics or similar public health crisis; and
- our ability to maintain a continued acceptable safety profile for our therapies following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, accounting, auditing, tax services, and insurance costs.

We expect that our general and administrative expenses will increase as our organization and grows in the future to support continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to for outside consultants, attorneys, and accountants, among other expenses. Additionally, we expect to incur increased expenses associated with being a public company, including costs of additional personnel, accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Results of Operations

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

	Three Months Ended June 30,				Six Months Ended June 30,				Three Months Ended September 30,				Nine Months Ended September 30,			
	2023	2022	Dollar Change	% of Change	2023	2022	Dollar Change	% of Change	2023	2022	Dollar Change	% of Change	2023	2022	Dollar Change	% of Change
Revenue:																

Research and development revenue under collaboration agreement	$ 2,004	$ 382	$ 1,622	425%	$ 7,316	$ 3,766	$ 3,550	94%	$ 1,185	$ 6,402	$ (5,217)	(81)%	$ 8,501	$ 10,168	$ (1,667)	(16)%
Operating expenses:																
Research and development	15,172	15,488	(316)	(2)%	30,723	29,831	892	3%	14,654	18,850	(4,196)	(22)%	45,378	48,682	(3,304)	(7)%
General and administrative	5,322	5,845	(523)	(9)%	10,598	11,848	(1,250)	(11)%	6,034	5,428	606	11%	16,632	17,276	(644)	(4)%
Total operating expenses	20,494	21,333	(839)	(4)%	41,321	41,679	(358)	(1)%	20,688	24,278	(3,590)	(15)%	62,010	65,958	(3,948)	(6)%

Loss from operations	($	18,490)	($	20,961)	2,471	(12)%	($	34,005)	($	37,913)	3,908	(10)%	($	193,503)	($	171,076)	(1,627)	9%	($	553,095)	($	550,907)	(2,281)	(4)%
Other income, net	$	1,375	$	4,605	(1,930)	(59)%	$	2,671	$	2,085	586	28%	$	21,602	$	15,386	6,216	40%	$	48,322	$	41,710	6,612	16%
Net loss	($	17,115)	($	20,149)	3,034	(16)%	($	31,334)	($	37,133)	5,799	(16)%	($	171,901)	($	171,338)	(563)	0%	($	504,773)	($	509,197)	4,424	(1)%

Revenue

The research and development revenue under collaboration agreement is related to the Bristol-Myers Squibb Collaboration Agreement for the IK-175 and IK-412 programs which was executed in January 2019. The increase decrease in revenue during the three months ended June 30, 2023 September 30, 2023, as compared to the same period in the prior year, was primarily due to an increase in manufacturing activities as a change in estimate made result of the substantial completion of manufacturing efforts related to the IK-412 program during the period three months ended June 30, 2022 of the development services expected to be performed during the term of the Bristol-Myers Squibb Collaboration Agreement related to IK-175. September 30, 2022. The increase decrease in revenue during the six nine months ended June 30, 2023, as compared to the same period in the prior year, September 30, 2023 was primarily due to the decision to stop the IK-175 head and neck study prior to enrolling any

participants in order to direct resources towards

completing the data package for the Bristol-Myers Squibb partnership, which is eligible for opt-in until early January 2024.

Research and Development Expenses

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

	Three Months Ended June 30,				Six Months Ended June 30,				Three Months Ended September 30,				Nine Months Ended September 30,			
	2023	2022	Dollar Change	% of Change	2023	2022	Dollar Change	% of Change	2023	2022	Dollar Change	% of Change	2023	2022	Dollar Change	% of Change
Direct research and development expenses by program:																
IK-930	$ 3,899	$ 2,514	$ 1,385	55%	$ 6,728	$ 5,368	$ 1,360	25%	$ 2,335	$ 2,561	$ (226)	(9)%	$ 9,063	$ 7,929	$ 1,134	14%
IK-175	627	1,505	(878)	(58)%	1,896	2,762	(866)	(31)%	391	2,046	(1,655)	(81)%	2,288	4,808	(2,520)	(52)%

IK-595	2,037	1,768	269	15%	3,902	3,055	847	28%	1,862	2,293	(431)	(19)%	5,764	5,349	415	8%
Other assets, discovery, and early stage programs	2,031	3,480	(1,449)	(42)%	4,132	6,636	(2,504)	(38)%	3,336	5,632	(2,296)	(41)%	7,468	12,268	(4,800)	(39)%
Research and development personnel and overhead expenses and unallocated	6,578	6,221	357	6%	14,065	12,010	2,055	17%	6,730	6,318	412	7%	20,795	18,328	2,467	13%
Total research and development expenses	$ 15,172	$ 15,488	$ (316)	(2)%	$ 30,723	$ 29,831	$ 892	3%	$ 14,654	$ 18,850	$ (4,196)	(22)%	$ 45,378	$ 48,682	$ (3,304)	(7)%

During the three and six nine months ended June 30, 2023 September 30, 2023, research and development expenses decreased $0.3 million $4.2 million and increased $0.9 million $3.3 million, respectively. The changes in research and development expense for the three and six nine months ended June 30, 2023 September 30, 2023 compared to the same periods in the prior year, were primarily due to decreases in clinical trial costs related to IK-175, and decreases in other discovery and early stage programs as a result of the Company prioritizing its focus on advancing its clinical stage programs, partially offset by an increases in costs incurred to wind down Pionyr clinical trials. During the nine months ended September 30, 2023 IK-930 costs increased due to clinical trial costs and consulting fees. Additionally, fees and research and development unallocated costs for IK-595 increased $0.9 million during the six months ended June 30, 2023 compared to the same period in the prior year primarily due to increased manufacturing costs and toxicity studies in preparation for the upcoming IND submission. consulting fees.

General and Administrative Expenses

The following table summarizes our general and administrative expenses (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2023	2022	Dollar Change	% of Change	2023	2022	Dollar Change	% of Change
General and administrative	$ 5,322	$ 5,845	$ (523)	-9%	10,59 $ 8	11,84 $ 8	(1,25 $ 0)	-11%

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2023	2022	Dollar Change	% of Change	2023	2022	Dollar Change	% of Change
General and administrative	$ 6,034	$ 5,428	$ 606	11%	16,63 $ 2	17,27 $ 6	$ (644)	-4%

During the three and six months ended June 30, 2023 September 30, 2023, general and administrative expenses increased $0.6 million. The increase in general and administrative expenses was primarily attributable to an increase in legal expenses. During the nine months ended September 30, 2023, general and administrative expenses decreased $0.5 million and $1.3 million, respectively. $0.6 million. The decrease in general and administrative expenses was primarily attributable to a decrease in legal, consulting and insurance expenses.

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for several years, if ever. To date, we have financed our operations primarily through private placements of

preferred stock, from upfront payments from the Bristol-Myers Squibb Collaboration Agreement, from cash obtained from acquisitions, from common stock in our IPO and URO, and most recently, from common stock in our URO. through the acquisition of Pionyr. As of June 30, 2023 September 30, 2023, we had cash, cash equivalentsa nd equivalents and marketable securities of $157.3 million $196.9 million.

Cash Flows

The following table summarizes our sources and uses of cash (in thousands):

	Six Months Ended June 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net cash used in operating activities	$ (37,927)	$ (39,235)	$ (57,924)	$ (56,454)
Net cash provided by (used in) investing activities	11,874	(145,56 5)	43,768	(109,783)
Net cash provided by financing activities	37,002	1,070	75,920	1,094
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 10,949	(183,73 $ 0)	$ 61,764	$ (165,143)

Operating Activities

Cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support the business. We have historically experienced negative cash flows from operating activities as we invested in developing our platform, drug discovery efforts, and related infrastructure. Net cash used in operating activities for the six nine months ended June 30, 2023 decreased September 30, 2023 increased by $1.3 million $1.5 million compared to the same period in 2022, due 2022. Cash used in operating activities was primarily related to a decrease in our net loss of $6.0 million $48.7 million, the payout of operating liabilities assumed in connection with the Pionyr Acquisition, partially offset by a decrease in deferred revenue.

Investing Activities

The net cash provided by investing activities was $11.9 million $43.8 million during the six nine months ended June 30, 2023 September 30, 2023, compared to net cash used in investing activities of $145.6 million $109.8 million during the six nine months ended June 30, 2022 September 30, 2022. The net cash provided by investing activities was primarily due to proceeds from the sale and maturity of marketable securities of $59.1 million $109.1 million, offset by the purchase of marketable securities of $47.1 million $65.2 million during the six nine months ended June 30, 2023 September 30, 2023. The net cash used in investing activities was due to the sale and maturity of marketable securities of $29.5 million $81.2 million,

offset by the purchase of marketable securities of $175.0 million $189.9 million during the six nine months ended June 30, 2022 September 30, 2022.

Financing Activities

The increase in net cash provided by financing activities of $35.9 million $75.4 million primarily reflects the net cash received in connection with the Pionyr Acquisition of $39.5 million and the net cash proceeds received from our May 17, 2023 offering of common stock. stock of $37.4 million.

Funding Requirements

We expect to continue to incur significant expenses for the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development for, initiate clinical trials for, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company, including increased costs of accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents, and marketable securities as of June 30, 2023 September 30, 2023, will enable us to fund our operating expenses and capital expenditure requirements into 2026. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future operating and capital requirements will depend on many factors, including:

- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials f other potential product candidates we may develop, if any;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaborati agreements we might have at such time;

- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing anc distribution, for any of our product candidates for which we receive marketing approval;

- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our prod candidates receive marketing approval;

- the costs of preparing, filing, and prosecuting patent applications, obtaining, maintaining, and enforcing our intellectual property rights, and defending intellectual property-related claims;
- the in-licensing or acquisition of assets in line with our strategy;
- our headcount growth and associated costs, as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Any debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

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

On April 27, 2022, we filed a shelf registration statement on Form S-3 ("Shelf"), with the SEC, which covers the offering, issuance, and sale by us of up to an aggregate of $300.0 million of our common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a sales agreement with Jefferies LLC, as sales agent, to provide for the issuance and sale by us of up to $100.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf, which we refer to as the ATM "ATM Program." The Shelf was declared effective by the SEC on May 5, 2022. As of the date hereof, no sales have been made pursuant to the ATM Program.

Contractual Obligations

We have a non-cancelable operating lease agreement for our office, lab, and animal care facility space in our Boston, Massachusetts corporate headquarters. We expect lease payments under this commitment to total $1.8 million in 2023 and increase annually through the lease expiration in 2026. Our total future minimum lease payments for each of the next five years and in total are included in Note 14 in our Annual Report on Form 10-K that was filed with the SEC on March 14, 2023.

Additionally, in connection with the Pionyr Acquisition, we acquired an operating lease agreement for office and lab space in San Francisco, California. The space is currently vacant and we are actively seeking a tenant to sublease the space.

We expect the total future minimum lease payments from October 2023 to lease expiration in April 2027 to be $8.1 million.

We enter into contracts in the normal course of business with CROs and CMOs for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts typically, do not contain any minimum purchase commitments and are generally cancelable by us, typically upon prior notice of 30 days. Payments due upon cancelation typically consist only of payments for services provided and expenses incurred up to the date of cancelation.

We may incur potential contingent payments upon our achievement of clinical, regulatory, and commercial milestones, as applicable, or that we may be required to make royalty payments under license agreements we have entered into with various entities pursuant to which we have in-licensed certain intellectual property such as our patent license agreement with the University of Texas at Austin and our license agreement with AskAt, Inc. Austin. Due to the uncertainty of the achievement and timing of the events requiring payment under these agreements, the amounts to be paid by us are not fixed or determinable at this time and have not been included in the table above.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in

these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. During the six nine months ended June 30, 2023 September 30, 2023, there were no material changes to our critical accounting policies from those described in our Annual Report on Form 10-K that was filed with the SEC on March 14, 2023.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Emerging Growth Company

In April 2012, the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") was enacted. Section 107 of the JOBS Act provides that an "emerging growth company," or an EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended ("the Securities Act"), for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our IPO.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until (i) the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250.0 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenues are $100.0 million or more during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide this the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship

of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2023 September 30, 2023, the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There As permitted by guidance issued by the SEC that an assessment of internal control over financial reporting of a recently acquired business may be omitted from management's evaluation of disclosure controls and procedures, management excluded an assessment of the internal controls of Pionyr, which we acquired on August 4, 2023, from its evaluation of the effectiveness of our disclosure controls and procedures. We are in the process of integrating Pionyr into our system of internal control over financial reporting.

Other than with respect to the integration of Pionyr into our system of internal control over financial reporting, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. In evaluating the Company and our business, careful consideration should be given the risks described below, as well as the other information in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Limited Operating History, Financial Position, and Capital Requirements

We are a targeted oncology company with a limited operating history.

We commenced operations in 2016 and are a targeted oncology company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Since our inception, we have devoted substantially all of our efforts to organizing and staffing our company, acquiring intellectual property, business planning, raising capital, conducting discovery, research and development activities, and providing general and administrative support for these operations. We have no products approved for commercial sale and, therefore, have never generated any revenue from product sales, and we do not expect to in the foreseeable future. We have not obtained regulatory approvals for any of our product candidates, and there is no assurance that we will obtain approvals in the future. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had, and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Our net losses were $31.3 million $48.7 million and $37.3 million $54.7 million for the six nine months ended June 30, 2023 September 30, 2023 and 2022, respectively. We had an accumulated deficit of $245.6 million $262.9 million as of June 30, 2023 September 30, 2023. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to increase significantly in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain regulatory approval for our product candidates, we will incur significant sales, marketing, and manufacturing expenses. As a public company, we will continue to incur additional costs that we did not incur as a private company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price

to fluctuate or decline. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- our ability to attract, hire, and retain qualified personnel;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or a other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully open clinical trial sites and recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such appro we may receive;

- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates and products, should they receive regulatory approval, which r vary depending on the quantity of production and the terms of our agreements with manufacturers; expenditure that we will or may incur to develop additional product candidates;
- the level of demand for our products should they receive regulatory approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We have no products approved for commercial sale and have not generated any revenue from product sales.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have generated minimal collaborative revenue from our product candidates and have not generated revenue from product sales, and we do not expect to generate any revenue from the sale of products in the near future. We do not expect to generate significant

revenue unless and until we obtain regulatory approval of, and begin to sell, one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our ongoing and planned preclinical and clinical studies for our programs;
- timely file and the acceptance of IND, for our programs in order to commence future clinical trials;
- successfully enroll subjects in, and complete, our ongoing and planned clinical trials;
- initiate and successfully complete all safety and efficacy studies required to obtain U.S. and foreign regulatory approval for our product candidates;
- establish commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinica supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community, and third-party payors;
- position our products to effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement;
- enforce and defend intellectual property rights and claims; and
- maintain a continued acceptable safety profile of our products following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We will require additional capital to finance our operations, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed or on terms acceptable to us, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

The development of pharmaceutical products is capital-intensive. We are currently advancing multiple targeted oncology programs through preclinical development toward identification of potential therapeutic candidates and subsequent planned IND filings. Additionally, we are conducting Phase 1 clinical trials of two of our for multiple product candidates IK-930 and IK-175, and we plan to submit an IND to the FDA for conduct clinical trials of our MEK-RAF complex inhibitor, IK-595, other product candidates in the second half of 2023 and initiate a Phase 1 clinical trial shortly thereafter. future. Consequently, we expect our expenses to significantly increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate and complete clinical trials of, and seek regulatory approval for, our product candidates. In addition, depending on the status of regulatory approval or, if we

obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current or future product candidates or otherwise expand more rapidly than we presently anticipate. We also continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate certain of our research and development programs or future commercialization efforts.

On May 17, 2023, we completed a URO of common stock pursuant to which we issued and sold 6,110,000 shares of our common stock at a purchase price of $6.55 per share. On August 4, 2023, we acquired Pionyr, in accordance with the terms of the Merger Agreement. Under the terms of the Merger Agreement, at the closing of the Merger, we acquired all of Pionyr's assets, including approximately $43 million in net cash at the time of closing, and we issued the holders of Pionyr common stock a total of 1,800,652 shares of the Company's common stock (including 153,121 shares of our non-voting common stock) at the purchase price of $7.15 per share and we 4,153,439 shares of Series A Preferred Stock, also at the purchase price of $7.15 per share, each share of which is convertible into one (1) share of the Company's common stock, subject to certain conditions. We expect that the net proceeds from the URO and acquisition of Pionyr, together with our existing cash, cash equivalents, and marketable securities, are sufficient to fund our operations into 2026. However, our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of product discovery, preclinical and clinical development, laboratory testin and clinical trials for our product candidates;
- the scope, prioritization, and number of our research and development programs;
- the costs, timing, and outcomes of regulatory reviews of our product candidates;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under our existing collaboration agreements or any additional collaboration agreements we may establish;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under futur collaboration agreements, if any;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for clinical and commercial production;
- costs related to the development of any companion diagnostics we may use in the future; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical development testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if

approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

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 product candidates. Disruptions in the financial markets in general and the recent volatility in

the capital markets may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product that has received

regulatory approval or be unable to expand our operations or otherwise capitalize on our business opportunities as desired, which could materially affect our business, financial condition and results of operations.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances alliances. and licensing arrangements. We do not have any committed external source of funds. The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of those securities may include liquidation or other preferences that may materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling, or licensing intellectual property rights, and making capital expenditures, declaring dividends or other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to meet certain milestones in connection with debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies or product

candidates or otherwise agree to terms unfavorable to us which could have a material adverse effect on our business, operating results, and prospects.

We also could be required to seek funds through arrangements with additional collaborators or otherwise at an earlier stage than otherwise would be desirable. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant licenses on terms that may not be favorable to us or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves, any of which may have a material adverse effect on our business, operating results and prospects.

Risks Related to the Development of our Targeted Oncology and Other Programs and Product Candidates

We have never successfully completed any clinical trials for our oncology programs, and we may be unable to do so for any product candidates we develop. Certain of our oncology programs are still in preclinical development and may never advance to clinical development.

We have not yet demonstrated our ability to successfully complete clinical trials, including large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. IK-930 is We have multiple programs in clinical development, currently in a Phase 1 clinical trial. However, our other targeted oncology programs, including IK-595, are still in preclinical development and IND enabling studies, and may never advance to early clinical development.We are currently advancing additional early-stage targeted oncology programs through preclinical development toward potential therapeutic candidates and subsequent IND. We may not be able to file such IND or INDs for any of our other product candidates on the timelines we expect, if at all. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their positions, including, but not limited to, regarding the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or result in the composition of stricter approval conditions than we currently expect. Successful completion of our clinical trials is a prerequisite to submitting a New Drug Application ("NDA") to the FDA, marketing authorization application ("MAA"), to the European Medicines Agency ("EMA"), or other marketing applications to regulatory authorities in other jurisdictions, for each product candidate and, consequently, the regulatory approval of each product candidate. IK-175 is also currently in clinical development. We are conducting a Phase 1 trial with IK-175 in patients with bladder cancer with activated AHR. However, we do not know whether these or any of our future clinical trials will begin on time or be completed on schedule, if at all.

If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product

candidates or other testing, if the results of these trials or tests are not positive, or are only modestly positive, or, if there are safety concerns, we may:

- not obtain regulatory approval at all;

29

- be delayed in obtaining regulatory approval for our product candidates;

26

- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements; or
- experience having the product removed from the market after obtaining regulatory approval.

Our programs are focused on the development of oncology therapeutics for patients with genetically defined or biomarker-driven cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to approved or marketable products.

The discovery and development of oncology therapeutics for patients with genetically defined or biomarker-driven cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work, that the genetic alterations targeted by our programs drive the formation and spread of cancer, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. The patient populations for our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients with targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to our product candidates and the ability to identify such alterations. Furthermore, even if we are successful in identifying patients with specific target alterations, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type, commercialize our product candidates and achieve profitability.

Clinical product development involves a lengthy and expensive process, with an uncertain outcome.

Our preclinical studies and future and ongoing clinical trials may not be successful. Currently, we have two multiple programs in early clinical development and our other targeted oncology programs are in preclinical development. It is impossible to predict when, or if, any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take

many years to complete and outcomes are uncertain. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Our preclinical studies and future and ongoing clinical trials may not be successful.

If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we may engage third parties to develop or otherwise obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our product candidates. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our products that receive regulatory approval. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory, and logistical challenges. The FDA and comparable foreign regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

We intend to rely on third parties for the design, development, and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. 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 product 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 therapeutic product candidates themselves, 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 these therapeutic product candidates, or

experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain regulatory approval, and we may not realize the full commercial potential of any of these therapeutic products that obtain regulatory approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic product candidates.

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

From time to time, we may publicly disclose interim, top-line, or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received all of the necessary data or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary, interim, or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary top-line data we previously published. As a result, preliminary, interim, and top-line data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the price of our common stock to fluctuate or decline.

Further, regulatory agencies and others 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 adversely impact the potential of the particular program, the likelihood of obtaining regulatory approval of the particular product candidate, commercialization of any approved product and the business prospects of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the preliminary, interim, or top-line data that we report differ from actual results, or if regulatory authorities or others, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product

candidates may be significantly impaired, which could materially harm our business, operating results, prospects, or financial condition.

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

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

- we may receive feedback from regulatory authorities that require us to modify the design or implementation of o preclinical studies or clinical trials or to delay or terminate a clinical trial;
- regulators, institutional review boards ("IRBs") or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- preclinical studies or clinical trials of our product candidates may fail to show safety or efficacy or otherwise produ negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinica studies or clinical trials, or we may decide to abandon product research or development programs;

- preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significan results across tumor types or indications;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical t or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clini trials, fail to meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical t protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a findin that the participants in our clinical trials are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our produ candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise fror preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and
- regulators may revise the requirements for approving our product candidates, or such requirements may not be we currently anticipate.

We could encounter delays if a clinical trial is suspended or terminated by us, including upon the recommendation of the Safety Monitoring Committee ("SMC") if applicable for such trial, by the IRBs of the institutions at which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including, but not limited to, failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with, among other considerations, our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Moreover, principal investigators for our current and future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. Such an outcome could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

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

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

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

or as needed to provide appropriate statistical power for a given trial. For example, because we are focused on patients with specific

genetic mutations or biomarkers for the development of our targeted oncology programs, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

We may experience difficulties with identifying specific patient populations for any biomarker-defined trial cohorts. The patient eligibility criteria defined in our trial protocols, including biomarker-driven identification may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria. We will also rely on the willingness and ability of clinicians to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials.

In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as do our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

In addition to the competitive trial environment, the eligibility criteria of our ongoing and planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their cancer is either severe enough or not too advanced to include them in a study. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit, or enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed.

We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, limiting our ability to identify patients with the targeted genetic mutations for our clinical trials. Further, if we are required to develop companion diagnostics and are unable to include patients with the targeted genetic mutations, this could compromise our ability to seek participation in the FDA's

expedited review and development programs, including breakthrough therapy designation and fast track designation, or otherwise seek to accelerate clinical development and regulatory timelines. Patient enrollment may be affected by other factors, including:

- the severity of the disease under investigation;
- the efforts to obtain and maintain patient consents and facilitate timely enrollment in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- reporting of the preliminary results of any of our clinical trials; and
- factors we may not be able to control that may limit patients, principal investigators or staff or clinical site availab

We anticipate that certain of our current product candidates and future product candidates will be used in combination with third-party drugs or biologics, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.

Certain of our current product candidates and any future product candidates have the potential to be administered in combination with other targeted therapies or checkpoint inhibitor immunotherapies, or and other standards of care, like chemotherapies, targeted therapies, or radiotherapy. For example, through our clinical supply collaboration with AstraZeneca, we plan to explore IK-930 in combination with AstraZeneca's EGFR inhibitor, osimertinib, and we are currently evaluating IK-175 in combination with nivolumab, which is marketed by Bristol-Myers Squibb. Our ability to develop and ultimately commercialize our current programs and product candidates and any future programs or product candidates used in combination with osimertinib, nivolumab, or other checkpoint inhibitor immunotherapies or other targeted therapies, will depend on our ability to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs or biologics on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing targeted therapies checkpoint inhibitor immunotherapies or other comparator therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable

therapies. If any of these occur, our business, financial condition, operating results, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. The FDA, other U.S. regulatory agencies and/or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the combination therapy and not our current product candidates and any future product candidates. Moreover, following product approval, the FDA, other U.S. regulatory agencies and/or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the other product, quality, manufacturing and supply issues with respect to the other product, and changes to the standard of care.

In the event that Bristol-Myers Squibb, AstraZeneca, or any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing targeted therapies, checkpoint inhibitor immunotherapies or other combination agents. Additionally, should the supply of products from any current or future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source an alternative supply, or are unable to do so on commercially reasonable terms, our business, financial condition, operating results, stock price, and prospects may be materially harmed.

Results from early preclinical studies and clinical trials of our programs and product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our programs and product candidates. If we cannot replicate the results from our earlier preclinical studies and clinical trials of our programs and product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Any results from our early preclinical studies and clinical trials of our targeted oncology and immune-signaling program or our product candidates may not necessarily be predictive of the results from later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies and clinical trials of our product candidates according to our current development timeline, the results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical, and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval.

We may not be able to file INDs, or similar applications for our programs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA or other regulatory authorities may not permit us to proceed.

We plan to nominate multiple development candidates stemming from our RAS-pathway and additional Hippo pathway research programs. We plan to progress candidates to IND or similar application, applications, however, we may not be able to file such INDs or similar applications on the timelines we expect. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that it will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or similar applications to a new IND or similar application. Any failure to file INDs or similar applications on the timelines we expect or to obtain regulatory approvals for our planned clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

Our clinical trials or those of our current or future collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex, and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Because our targeted oncology programs and our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later

stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically

meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented from, or delayed in, obtaining regulatory approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Although we are currently conducting Phase 1 clinical trials of two multiple of our product candidates, IK-930 and IK-175, it is likely, as is the case with many oncology therapies, that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our

trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. In addition, our product candidates could cause undesirable side effects that we have not yet observed. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. Most product candidates that commence clinical trials are never approved as products, and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development or regulatory approval of any of our product candidates.

We plan to develop certain of our product candidates, in combination with one or more cancer therapies. The uncertainty resulting from the use of our product candidates, in combination with other cancer therapies, may make it difficult to accurately predict side effects in future clinical trials. As is the case with many treatments for cancer and rare diseases, it is likely that there may be side effects associated with the use of our product candidates. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an IRB may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, operating results, financial condition, and prospects.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, and utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Some of our product candidates modulate pathway pathways for which there are currently no approved or effective therapies, which may result in uncertainty. We select programs for cancer driver targets based on compelling biological rationale. We explore new programs based on extensive preclinical data analysis which sometimes cannot predict efficacy or safety in humans.

Some of our product candidates utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects. We utilize structural biology in tight integration with our medicinal chemistry and biology capabilities to predict and design the compounds that will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. A disruption in any of these capabilities may have significant adverse effects in our ability to expand our pipeline of product candidates, and we cannot predict whether we will continue to have access to these capabilities in the future to support our pipeline development. In addition, there can be no assurance that we will be able to rapidly identify, design and synthesize the necessary compounds or that these or other problems related to the development of product candidates will not arise in the future, which may cause significant delays or we raise problems we may not be able to resolve.

Regulatory approval of novel product candidates such as ours can be more expensive, riskier, and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. The novelty of the mechanism of action of any of our product candidates may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development, and

manufacturing positions. If our inhibitors utilize a novel mechanism of action that has not been the subject of extensive study compared to more well-known product candidates, there is also an increased risk that we may discover previously unknown or

unanticipated adverse effects during our preclinical studies and clinical trials. Any such events could adversely impact our business prospects, operating results and financial condition.

We may in the future conduct clinical trials for our product candidates outside the United States, and the FDA, the EMA, the Medicines and Healthcare products Regulatory Agency ("MHRA") and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future conduct additional clinical trials outside the United States, including in Europe, the United Kingdom, Australia, or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States

population and United States medical practices, (ii) the trials were performed by clinical investigators of recognized competence, and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. The EMA, the MHRA and many other comparable foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, the EMA, the MHRA, or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States, the European Union, the United Kingdom, or the applicable jurisdiction. If the FDA, the EMA, or the MHRA, or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving regulatory approval or clearance for commercialization in the applicable jurisdiction.

Although we intend to explore other therapeutic opportunities in addition to the programs and product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candida
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

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

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and

export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. Before we can commercialize any of our product candidates, we must obtain regulatory approval.

Currently, all of our product candidates are in discovery, preclinical or clinical development, and we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval may be delayed, if obtained at all. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in regulatory approval policies during the development period, changes in or enactment of additional statutes or regulations, or changes in regulatory review policies for each submitted NDA, Premarket Approval Application ("PMA"), or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clini trials;
- we may not be able to enroll a sufficient number of patients in our clinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities tha product candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable tc identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable for regulatory authorities for approval;
- we may be unable to demonstrate that a product 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 preclinica studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission o NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufactu processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; an
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly cha such that our clinical data are insufficient for approval.

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

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

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

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Such global outbreaks of infectious diseases could materially and adversely impact our operations, including, without limitation, our preclinical studies or clinical trial operations and our ability to recruit and retain patients and principal investigators and site staff. For example, similar to other biopharmaceutical companies, we may experience delays in initiating IND-enabling

studies, protocol deviations, enrolling our clinical trials, or dosing of patients in our clinical trials, as well as in activating new trial sites. Any negative impact COVID-19 or a similar public health crisis has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

These, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operation and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on global economies and financial markets, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates.

We may need to reformulate our product candidates which could require additional nonclinical studies or clinical trials and delay the development or regulatory approval of such product candidates.

New risks and side effects associated with our product candidates may be discovered during clinical testing. Our product candidates also may experience stability issues. For these or other reasons, we may need to reformulate our product candidates. Such reformulation may require us to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our product candidate. Reformulating a product candidate may also result in a delay in continuing a clinical trial. There can be no assurance that we will not experience delays in the completion of a clinical trial or in the commencement and completion of our future trials due to the need to reformulate our product candidates and subsequently discuss with or receive authorization from regulatory authorities to implement these changes in clinical trials. Additionally, reformulating a product candidate may cause us to experience a shortage in supply or cause the cost to manufacture our product candidate to increase. Any reformulation of our product candidates could substantially increase the costs and expenses of developing our product candidates and delay such development and marketing approval.

Risks Related to Commercialization

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

The development and commercialization of new products in the biopharmaceutical and related industries is highly competitive. We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address structural biology-guided chemistry-based drug design to develop therapies in the fields of cancer and genetic diseases. There are other companies focusing on targeted oncology to develop therapies in the fields of cancer and other diseases. We also compete more broadly across the market for cost-effective and reimbursable cancer treatments. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or

commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety, and convenience of our products. We believe principal competitive factors to our business include, among other things, our ability to identify biomarkers, ability to successfully transition research programs into clinical development, ability to raise capital, and the scalability of the platform, pipeline, and business.

Many of the companies that we compete against or which we may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic

diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. If these or other barriers to entry do not remain in place, other companies may be able to more directly or effectively compete with us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their products sooner than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition and availability of reimbursement from government and other third-party payors.

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

The incidence and prevalence for target patient populations of our programs and product candidates have not been established with precision. Our most advanced targeted oncology product candidate, IK-930, is an oral, TEAD1-selective, small molecule inhibitor of the Hippo signaling pathway. The Hippo pathway is genetically altered in approximately 10% of all cancers and these genetic alterations are generally associated with poor clinical outcomes. The Hippo pathways pathway is also associated with mechanisms of resistance to targeted therapeutics and could represent a larger population of patients. We are conducting additional research in the Hippo pathway to identify potential next generation programs. Additionally, we are currently evaluating IK-175 in a Phase 1 clinical trial in patients with solid tumors and patients with urothelial carcinoma, including those with activated AHR. AHR amplifications have been described in approximately 5% to 22% of bladder cancer patients. We are also conducting IND-enabling studies on In addition, our IK-595 our program candidate is an oral, small molecule MEK-RAF complex inhibitor, for which an IND submission to the FDA is planned for the second half of 2023. molecular glue. We have additional early-stage programs evaluating multiple nodes in the RAS pathways. pathway. KRAS mutations in the RAS signaling pathway occur in approximately 26% of all cancers. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our programs and product candidates, are based on our estimates.

The total addressable market opportunity will ultimately depend upon, among other things, the diagnosis criteria included in the final label, the indications for which our product candidates are approved for sale, acceptance by the medical community and patient access, product pricing, and reimbursement. The number of patients with the cancers and solid tumors for which our product candidates may be approved as treatment may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect our business.

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

We have never commercialized a product candidate for any indication. Even if our current product candidates and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not become profitable or may be significantly delayed in achieving profitability. Market acceptance of our current product candidates and any future product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective or safer treatments enter the market. If public perception is influenced by claims that the use of cancer immunotherapies targeted oncology is unsafe, whether related to our or our competitors' products, our products may not be accepted by the general public or the medical community. Future adverse events in targeted oncology, immune-oncology or the biopharmaceutical industry could also result in greater governmental

regulation, stricter labeling requirements, and potential regulatory delays in the testing or approvals of our product candidates.

36

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related

39

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treatments will be available from government health administration authorities, private health insurers, and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

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

- the efficacy of our current product candidates and any future product candidates as single agents and in combination with marketed checkpoint inhibitor immunotherapies, targeted agents, and other combination ager
- the commercial success of the checkpoint inhibitor immunotherapy drugs, targeted agents, and other combinatic agents with which our products may be co-administered;
- the prevalence and severity of adverse events associated with our current product candidates and any future product candidates or those products with which they may be co-administered;
- the clinical indications for which our product candidates are approved and the approved claims that we may mak for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatc authorities, including potential limitations or warnings for our current product candidates and any future product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our current product candidates and any future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our current product candidates and any future product

candidates and any products with which they are co-administered;

- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third party payors, including government healthcare programs such as Medicare and Medicaid and other healthcare payors;
- the price concessions required by third-party payors to obtain coverage;
- the willingness of patients to pay out-of-pocket in the absence of adequate coverage and reimbursement;
- the extent and strength of our marketing and distribution of our current product candidates and any future prod candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used c that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect tc our current product candidates and any future product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our current product candidates and any future product candidates, as well a competitive products;
- our ability to offer our current product candidates and any future product candidates for sale at competitive pric
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapie
- the extent and strength of our third-party manufacturer and supplier support;

37

- the actions of companies that market any products with which our current product candidates and any future product candidates may be co-administered;
- the approval of other new products;

40

- adverse publicity about our current product candidates and any future product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement by government authorities for new products are typically made by CMS, Centers for Medicare and Medicaid Services ("CMS"), since CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. However, one payer's determination to provide coverage for a product does not assure that other payers will also provide coverage for the drug product. Further, a payer's decision to provide coverage for a drug product does not imply that the payor will provide adequate reimbursement. Reimbursement agencies in the European Union may be more conservative than CMS. Factors payors consider in determining reimbursement are based on whether the product is:

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

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

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our Phase 1 clinical trials of IK-930 and IK-175, and expect to rely on third parties to conduct clinical trials for our other targeted oncology programs, including IK-595, as well as investigator-sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates, including our current Phase 1 clinical trials of IK-930 and IK-175, as well as

any other current product candidates, including IK-595, or future product candidates that may emerge from our targeted oncology programs.

candidates.

We rely and expect to continue to rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements, and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We, our principal investigators and our CROs are required to comply with regulations, including good clinical practices ("GCPs"), for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area ("EEA") and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators, and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with current Good Manufacturing Practices ("cGMP") regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, significantly increase our expenditures and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we designed our current ongoing clinical trials, of IK-930 and IK-175, and intend to design the future clinical trials for our product candidates, including IK-595, these trials are conducted by CROs and we expect CROs will conduct all of our future clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying

entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the principal investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us, or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our principal investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs do not successfully carry out their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials,

whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from

investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the

investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

We have entered into collaborations and may enter into additional collaborations in the future, and we might not realize the anticipated benefits of such collaborations.

Research, development, commercialization and/or strategic collaborations, including the existing collaboration that we have with Celgene Corporation (now part of Bristol-Myers Squibb), are subject to numerous risks, which include the following:

- collaborators may have significant control or discretion in determining the efforts and resources that they will ap to a collaboration, and might not commit sufficient efforts and resources or might misapply those efforts and resources;
- we may have limited influence or control over the approaches to research, development, and/or commercializati of product candidates in the territories in which our collaboration partners lead research, development and/or commercialization;
- collaborators might not pursue research, development, and/or commercialization of collaboration product candidates or might elect not to continue or renew research, development and/or commercialization programs based on nonclinical and/or clinical trial results, changes in their strategic focus, availability of funding or other factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators might delay, provide insufficient resources to, or modify or stop research or clinical development fo collaboration product candidates or require a new formulation of a product candidate for clinical testing;
- collaborators with sales, marketing and distribution rights to one or more product candidates might not commit sufficient resources to sales, marketing and distribution or might otherwise fail to successfully commercialize thos product candidates;
- collaborators might not properly maintain or defend our intellectual property rights or might use our intellectual property improperly or in a way that jeopardizes our intellectual property or exposes us to potential liability;
- collaboration activities might result in the collaborator having intellectual property covering our activities or prod candidates, which could limit our rights or ability to research, develop and/or commercialize our product candidat
- collaborators might not be in compliance with laws applicable to their activities under the collaboration, which co impact the collaboration and us;
- disputes might arise between a collaborator and us that could cause a delay or termination of the collaboration o result in costly litigation that diverts management attention and resources; and

- collaborations might be terminated, which could result in a need for additional capital to pursue further research, development, and/or commercialization of our product candidates.

In addition, funding provided by a collaborator might not be sufficient to advance product candidates under the collaboration. For example, although Bristol-Myers Squibb provided us with an $80.5 million upfront payment and a $14.5 million equity investment upon entering into that certain master collaboration agreement the Bristol-Myers Squibb Collaboration Agreement with Celgene Corporation (now Bristol-Myers Squibb), we might need additional funding to advance product candidates prior to the completion of a Phase 1b clinical trial, the clinical milestone when Bristol-Myers Squibb must decide whether to exercise its exclusive license rights to IK-175 or IK-412. On November 20, 2019, Bristol-Myers Squibb acquired Celgene Corporation and Bristol-Myers Squibb may take a different approach to our collaboration or determine not to continue the collaboration.

If a collaborator terminates a collaboration or a program under a collaboration, including by failing to exercise a license or other option under the collaboration, whether because we fail to meet a milestone or otherwise, any potential revenue from the collaboration

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would be significantly reduced or eliminated. In addition, we will likely need to either secure other funding to advance research, development and/or commercialization of the relevant product candidate or abandon that program, the development of the relevant product candidate could be significantly delayed, and our cash expenditures could increase significantly if we are to continue research, development and/or commercialization of the relevant product candidates.

Any one or more of these risks, if realized, could reduce or eliminate revenue from product candidates under our collaborations, and could have a material adverse effect on our business, financial condition, results of operations, and/or growth prospects.

We contract with third parties for the manufacture of our product candidates for preclinical development and clinical testing, and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our products if any of our product candidates receive regulatory approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

If any CMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In such a scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any additional agreements with third-party manufacturers or do so on acceptable terms. Reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;

41

- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenier for us.

44

Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The third parties upon whom we rely for the supply of the active pharmaceutical ingredients used in our product candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients ("API") used in all of our product candidates are supplied to us from single-source suppliers. Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization.

We are also unable to predict how changing global economic conditions or potential global health concerns will further affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our

suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the API used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API from alternate sources at acceptable prices in a timely manner could impede, delay, limit, or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's own evaluation of a potential collaboration. Such factors a potential collaborator will use to evaluate a collaboration may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be

more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant

number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

In addition, any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the U.S. and other countries for our current or future product candidates, as well as for their respective compositions, formulations, methods used to manufacture them, and methods of treatment, in addition to successfully defending these patents against third-party challenges. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and abroad related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, in jurisdictions outside the U.S., a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Accordingly, any actual or purported co-owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co-ownership. Furthermore, patents have a limited lifespan. In the U.S., and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or

shortly after such candidates are commercialized. As a result, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until at least 18 months after the earliest priority date of patent filing, or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution 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. Further, with respect to certain pending patent applications covering our current or future product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. 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 technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may become involved in post-grant proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review, or interference proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office ("USPTO"), the European Patent Office ("EPO"), or in other countries. In addition, we may be subject to a third-party submission to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may allege that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by claiming to an administrative patent authority or judge that the invention was not patent-eligible, was not original, was not novel, was obvious, and/or lacked inventive step, and/or that the patent application filing failed to meet relevant requirements relating to description, basis, enablement, and/or support; in litigation, a competitor could claim that our patents, if issued, are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

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 we generally require all of our employees, consultants, and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we 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.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our

ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third-party may develop

a competitive drug that provides benefits similar to one or more of our current or future product candidates, but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such

competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business.

Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition. Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain, or enforce such patent claims.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. We may miss a filing deadline for patent protection on these inventions.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse can, in some cases, be cured by payment of a late fee, or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the

relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent 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. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented, or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may

otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the

45

U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to

48

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establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions 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. 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. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third-party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Post-grant proceedings provoked by third-parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are

successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent,

misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third-party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third-party. If we later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third-party.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to damages or settlement costs resulting from claims that we or our employees have violated the intellectual property rights of third parties, or are in breach of our agreements. We may be accused of, allege or otherwise become party to lawsuits or disputes alleging wrongful disclosure of third-party confidential information by us or by another party, including current or former employees, contractors or consultants. In addition to diverting

attention and resources to such disputes, such disputes could adversely impact our business reputation and/or protection of our proprietary technology.

The intellectual property landscape relevant to our product candidates and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. For example, many of our employees were previously employed at other biotechnology or pharmaceutical companies. 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 we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

While certain activities related to development and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement under 35 U.S.C. §271(e)(1), upon receiving FDA approval for such candidates we or any of our future licensors or strategic partners may immediately become party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because

of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our current or future product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensiv and time-consuming to litigate and may divert our management's attention from our core business and may imp our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our current product candidates, including IK-930, IK-595, and IK-175, or future product candidates, or from using our proprietary technologies, unl the third-party licenses its product rights to us, which it is not required to do, on commercially reasonable terms c all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amoun and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclus which would permit third parties to use the same intellectual property to compete with us;
- redesigning our current or future product candidates or processes so they do not infringe, misappropriate or viol third-party intellectual property rights, which may not be possible or may require substantial monetary expenditu and time; and
- 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 substa adverse effect on the price of our common stock. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence c any of the foregoing could have a material adverse effect on our business, financial condition, results of operatior or prospects.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our current or future product candidates or proprietary technologies.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted in U.S. courts only with evidence that is "clear and

convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued and patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we

may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending third-party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our current or future product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our current or future product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against

us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our current or future product candidates, which could harm our business significantly.

We may be unable to obtain patent or other intellectual property protection for our current or future product candidates or our future products, if any, in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We may not be able to pursue patent coverage of our current or future product candidates in all countries. Filing, prosecuting and defending patents on current or future product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license 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.

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

We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

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

We may from time to time be party to license and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to

maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights 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 current or future product candidates, and what activities satisfy those diligence obligatic
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

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

Any granted patents we may own or in-license covering our current or future product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies

in the U.S. or abroad, including the USPTO and the EPO. A patent asserted in a judicial court could be found invalid or unenforceable during the enforcement proceeding. Administrative or judicial proceedings challenging the validity of our patents or individual patent claims could take months or years to resolve.

If we or our licensors or strategic partners initiate legal proceedings against a third-party to enforce a patent covering one of our current or future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, in the process of obtaining the patent during patent prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in such a way that they no longer cover our current or future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license, allow third parties to commercialize our current or future product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our future licensors' priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our current or future product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and current or future product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be

available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the current or future product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the U.S. and other countries could increase those uncertainties and costs. For example, the Leahy-Smith Act, signed into law in 2011, introduced provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first inventor to file" system. The Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

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. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our current or future product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad

that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. As mentioned above, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third-party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license may not lead to issued patents;

- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, r be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issu
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countrie where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks Related to Government Regulation

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

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could

result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

We may seek priority review designation for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review designation for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may seek orphan drug designation for certain of our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

As part of our business strategy, we may seek orphan drug designation for certain of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is a product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of more than 200,000 in the United States where there is no reasonable expectation that the cost of developing the product will be

recovered from sales in the United States. 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.

Similarly, in EU, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants an orphan designation in respect of a product if its sponsor can show that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (i) such condition affects no more than 5 in 10,000 persons in the EU when the application is made, or (ii) it is unlikely that, without the benefits derived from orphan status, sales of the product in the EU would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there must be no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if such a method exists, the product would be of a significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers.

We have received orphan drug designation from the FDA for IK-930 for the treatment of mesothelioma. Generally, if a product with an orphan designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing

application for the same product and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in EU. The EU market exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. The European Commission introduced a legislative proposal in April 2023 that, if implemented, could reduce the current ten-year marketing exclusivity period in the EU for certain orphan medicines to nine years (or five years for well-established use orphan medicines). Even if we obtain orphan drug exclusivity for any product candidates in addition to IK-930, that exclusivity may not effectively protect IK-930 or our other product candidate from competition because different products can be approved for the same condition.

Even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a product nor gives the product any advantage in the regulatory review or approval process. While we may

seek orphan drug designation for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

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

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

We have received fast track designation from the FDA for IK-930 for the treatment of unresectable NF2-deficient mesothelioma and for IK-175 in combination with immune checkpoint inhibitors in patients with advanced urothelial carcinoma who have progressed on or within three months of receiving the last dose of checkpoint inhibitors. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for fast track designation. We may seek fast track designation for some of our other product candidates. The FDA has broad discretion whether or not to grant this designation, so even if we believe another particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, as we have for IK-930 and IK-175, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

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

product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA generally requires that a

sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post approval confirmatory clinical trials, which must be completed with due diligence. FDORA gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such trials in a timely manner or if such post-approval trials fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory trial or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

The FDA, the EMA, the MHRA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, and such changes can be difficult to predict.

The FDA, the EMA, the MHRA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could

negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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 and 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. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. 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 In addition, government shutdowns could impact funding of the SEC and other government agencies on which our ability operations may rely, including those that fund research and development activities, is subject to access the public markets political process, which is inherently fluid and obtain necessary capital in order to properly capitalize and continue our operations.unpredictable.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of impactful legislative and regulatory changes to the health care system and legal framework that could impact our ability to sell our products profitably. In particular, in 2010 the ACA was enacted. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed

care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

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

In addition, other legislative changes have been proposed and adopted since the ACA was enacted:

- The U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which will remain in effect through 2032. Due to the federal Statutory Pay-As-You-G Act of 2010 (The SPAYGO), Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The SPAYGO resulted from the American Rescue Plan Act of 2021 and subsequent legislation in an effo to address the estimated budget deficit increases.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers a increased the statute of limitations period for the government to recover overpayments to providers from three five years. These laws and future laws may result in additional reductions in Medicare and other healthcare fundir and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulat approval or the frequency with which any such product candidate is prescribed or used.
- The Right to Try Act (2018), among other things, provides a federal framework for certain patients to access certai investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigati for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical tri and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- CMS has published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drug beginning January 1, 2020.
- In August 2022, the Inflation Reduction Act ("IRA") was signed into law. The IRA includes several provisions that m eventually impact our business, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D

beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. governme to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosim competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Furt under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program if they have one ra disease orphan designation and the only approved indication is for that rare disease. If a product receives multipl rare disease orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutional of the IRA's Medicare drug price negotiation program. The effect of IRA on our business and the healthcare indust in general is not yet known.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such heightened scrutiny resulted in several U.S. Congressional inquiries as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule

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that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general is not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order issued by President Biden, that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden Administration may reverse or otherwise change these measures,

both the Biden Administration and the U.S. Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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

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

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies, beyond those reductions which have already gone into effect. Such additional reductions could potentially lower the price that we receive for our products. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our products. It is not clear how other future potential changes to the ACA, or other similar measures, will change the reimbursement model and market outlook for our current and future product candidates.

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

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business once we begin commercializing our product candidates. Healthcare entities, physicians and other providers, and third-party payors play a primary role in the recommendation and prescription of any product

candidates for which we obtain regulatory approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain regulatory approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal Anti-Kickback Statute ("AKS") which prohibits, among other things, persons from knowingly and willful soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indire in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, arrangement, or recommendation of, any good, facility, item or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or

specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines penalties for each violation, plus up to three times the remuneration involved, which is also known as treble damages, imprisonment of up to ten years, and exclusion from government healthcare programs such as Medica and Medicaid. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers, c the one hand, and prescribers, purchasers and formulary managers, on the other. In addition, the government m assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for

purposes of the federal False Claims Act, or FCA, or federal civil money penalties. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims and civil monetary penalties laws, including the FCA, imposes criminal an civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingl presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulen and/or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal AKS constitutes a false of fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery which are known as qui tam suits and also referenced above;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of t payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or devic material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, payment for, healthcare benefits, items or services relating to healthcare benefits, items or services relating to

healthcare matters. Similar to the federal AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. Physician Payments Sunshine Act (the "Sunshine Act") and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program ("CHIP"), with specific exceptions, to report annually to CM information related to certain payments and other transfers of value to physicians, nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, and certified nurse midwives as well as teaching hospitals. Manufacturers are also required to disclose ownership and investment interests held by physicians anc their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH" and their respective implementing regulations including the Final Omnibus Rule published in January 2013, which impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the creation, maintenance, receipt, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicat to business associates, and gave state attorneys general new authority to file civil actions for damages or injuncti in federal courts to enforce the federal HIPAA laws and to seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of personal health information, other personal information, and privacy generally, many of which dif from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activ that potentially harm consumers; and
- federal price reporting laws, which would require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal AKS and FCA, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research

and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation ("GDPR"), which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and

often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with

an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement has led to an increasing number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with all applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions would likely be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against, settling and/or otherwise resolving any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and individual imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

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

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

damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure

safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Later discovery of previously unknown problems with a product, including adverse events of unanticipated

severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;

- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncomplian requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- clinical trial holds;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. Most notably, in the EEA and the UK, the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, is subject to the EU GDPR (with regards to the EEA) and the UK GDPR (with regards to the UK), as well as applicable national data protection legislation and requirements. In this document, "GDPR" refers to both the EU GDPR and the UK GDPR, unless specified otherwise. The GDPR are wide-ranging in scope and impose numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, requirements to conduct data protection impact assessments and taking certain measures when engaging third-party processors. Failure to comply with the requirements of the GDPR may result in warning letters, mandatory audits, orders to cease/change the use of data, and financial penalties, including fines of up to 4% of global revenues, or 20,000,000 Euro (£17.5 million for the UK), whichever is greater. The GDPR also 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.

The GDPR provides that EEA Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition.

The GDPR also include restrictions imposes strict rules on cross-border data transfers the transfer of personal data to countries outside the EEA that are not considered by the European Commission and UK government as providing "adequate" not deemed adequate for the transfer of such personal data by competent data protection to personal data authorities ("third countries"), including the United States in certain circumstances, unless a valid derogation exists or we incorporate a GDPR transfer mechanism (for example, (such as the European Commission approved Standard Contractual Clauses standard contractual clauses ("SCCs") and or the UK International Data Transfer Agreement/Addendum ("UK IDTA")) has been put in place.

61

Where relying on the SCCs or UK IDTA for into our agreements with third parties to govern such transfers of personal data transfers, we may also be required to and carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. assessments. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost and may result in us needing to make strategic considerations around where EEA and EEA/UK personal data is transferred located and which service providers we can utilize for the processing of EEA and EEA/UK personal data.

64

Although the UK is regarded as a third country under the EU GDPR, the European Commission has issued a decision an "Adequacy Decision" recognizing the UK as providing adequate protection under the EU GDPR ("Adequacy Decision") and, therefore, transfers of personal data originating in subject to the EEA EU GDPR to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government has also now introduced a Data Protection and Digital Information Bill ("UK (the "UK Bill") into the UK legislative process. The aim of process with the UK Bill is intention for this bill to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA EU data protection regime and threaten the UK Adequacy Decision from the European EU Commission. This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

Compliance with the GDPR and UK GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European and UK-based activities. Similar comprehensive data protection requirements exist in many other jurisdictions around the world and will have any

impact on any plans for expansion outside of the United States.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Relating to Employee Matters and Managing Growth

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

We are highly dependent on many of our key employees and members of our executive management team as well as the other principal members of our management, scientific and clinical team. Although we have entered into

employment letter agreements with certain of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and

62

clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

65

Recruiting and retaining qualified scientific, clinical, manufacturing and general and administrative personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our research, 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. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

In particular, we have experienced a very competitive hiring environment in Boston, Massachusetts, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

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

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial

information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Cyberattacks could include industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, including ransomware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial, or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. If we were to experience an attempted or successful cybersecurity attack of our information systems or data, the costs associated with the investigation, remediation and potential notification of the attack to counterparties, data subjects, regulators or others, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants, could be material. In addition, following any such attack, our remediation efforts may not be successful. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR or UK GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies, and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in the losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenue or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or

mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. By

way of example, the California Consumer Privacy Act ("CCPA"), as amended by the California Privacy Rights Ac,t Act creates individual privacy rights for California consumers

and increases the privacy and security obligations of entities handling certain personal data. 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.

Additionally, some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. Already, in the United States, we have witnessed significant developments at the state level. Laws similar to the CCPA have been passed in Montana, Texas, Iowa, Indiana, Tennessee, Connecticut, Colorado, Utah, and Virginia. twelve other states outside of California. While these new state laws incorporate many similar concepts, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of regulated businesses. The new laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. In addition to these comprehensive consumer privacy laws, a small number of states have also enacted laws focused on particular aspects of privacy. For example, the state of Washington has enacted a law that regulates the privacy of medical and health related information not subject to HIPAA and a small number of states have passed laws that regulate biometric information.

In addition, a number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. At the federal level, there is discussion of a new comprehensive data privacy law which, if passed, would help to streamline certain of our privacy obligations but would also introduce new stringent privacy and data security obligations that would apply to personal data collected from throughout the United States.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with U.S. and foreign and/or privacy data protection laws and regulations, it could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our

contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We may be unable to successfully integrate acquisitions, which may adversely impact our operations.

We have in the past and in the future may continue to acquire complementary businesses or technologies. Acquired technologies, products or businesses may not perform as we expect, and we may fail to realize anticipated synergies or results. In addition, our acquisition strategy may divert management's attention away from our existing business, and expose us to unanticipated problems or legal liabilities, including responsibility as a successor for undisclosed or contingent liabilities of acquired businesses or assets.

We have successfully integrated our past acquisitions of Arrys Therapeutics, Inc. or Amplify Medicines, Inc., however, if we are unsuccessful in integrating any future acquisitions, it could impede us from realizing all of the benefits of those acquisitions and could weaken our business operations or future prospectus. The integration process may disrupt our business and, if new technologies, products or businesses are not implemented effectively, may preclude the realization of the full benefits expected by us and could harm our results of operations. In addition, the overall integration of new technologies, products or businesses may result in unanticipated problems, expenses, liabilities and competitive responses. The difficulties of integrating an acquisition include, among other things:

- issues in integrating the target company's technologies, product candidates or capabilities with ours;
- maintaining employee morale and retaining key employees;
- integrating the culture of the target company with ours;
- preserving important strategic relationships and collaborations; and
- consolidating corporate and administrative infrastructures and eliminating duplicative operations.

64

In addition, even if the operations of an acquisition are integrated successfully, we may not realize the full benefits of the acquisition, including the synergies, pipeline expansion or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frame, or at all.

67

We expect to expand our development 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 August 1, 2023 November 1, 2023 we had 59 [57] full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we function as a public company and in the areas of product development, regulatory affairs and, if any of our product candidates receives regulatory

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, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to Our Common Stock

Pursuant to the terms of the Merger Agreement, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series A Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve this matter, and if they fail to do so our operations may be materially harmed.

Under the terms of the Merger Agreement, we agreed to take all action necessary under applicable law to call and hold a meeting of our stockholders to obtain the requisite approval for the conversion of all outstanding shares of Series A Preferred Stock issued in the merger into shares of our common stock, as required by the Nasdaq listing rules, within 45 days after the date that the definite proxy statement relating to the conversion is filed with the SEC. If our stockholders do not timely approve the conversion of our Series A Preferred Stock, then the holders of our Series A Preferred Stock may be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock, as described in our certificate of designation relating to the Series A Preferred Stock. If we are forced to settle a significant amount of the Series A Preferred Stock, it could materially affect our results of operations.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may also limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation entities affiliated with or managed by certain of our stockholders will hold an aggregate of 5,586,311 shares of our non-voting common stock, out of a total of 6,215,466 shares of our non-voting common stock issued and outstanding. Upon written notice, these entities could convert a portion of these shares of non-

voting common stock into up to an aggregate of 9.99% of our shares of common stock. Upon 61 days' prior written notice, these entities could convert all of their respective shares of non-voting common stock into shares of common stock. Consequently, the holders of our non-voting common stock who have exercised their option to make this conversion, will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

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

Under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended ("the Code") if a corporation undergoes an "ownership change" (generally defined as one or more shareholders or groups of shareholders who own at least 5 percent of the corporation's equity increasing their equity ownership in the aggregate by a greater than 50 percentage point change (by value) over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future or subsequent shifts in our stock ownership, some of which are outside our control. As of December 31, 2022, we had federal and state net operating loss carryforwards of approximately $108.9 million and $105.9 million respectively, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us. Furthermore, our ability to utilize our net operating losses or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As a result, the amount of the net operating loss and tax credit carryforwards presented in our consolidated financial statements could be limited and may expire unutilized. Under the current law, federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration. However, any such net operating loss carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020. State net operating loss carryforwards and other tax attributes may be similarly limited. Any such limitations may result in increased tax liabilities that could adversely affect our business, results of operations, financial position and cash flows.

We have commenced an at-the-market ("ATM") offering program to raise capital. Increased volatility and decreases in market prices of equity securities generally and of our common shares in particular may have an adverse impact on our willingness and/or ability to continue to sell our common shares through our ATM offering. Decreases in these sales would/could affect the cost or availability of equity capital, which could in turn have an adverse effect on our business, including current operations, future growth, revenues, net income and the market prices of our common shares.

In April 2022, we commenced an ATM program to raise capital. Under our ATM program, we have entered into a sales agreement to sell common shares, up to a maximum aggregate market value of $100.0 million, through one or more at-the-market offerings. Given the decrease in the market price of our common shares and volatility in the capital markets, we may not be willing or able to continue to raise equity capital through our ATM program. We may, therefore, need to turn to other sources of funding that may have terms that are not favorable to us, or reduce our business operations given capital constraints.

Alternative financing arrangements, if we pursue any, could involve issuances of one or more types of securities, including common stock, preferred stock, convertible debt, warrants to acquire common stock, or other securities. These securities could be issued at or below the then prevailing market price for our common shares. In addition, if we issue debt securities, the holders of the debt would have a claim to our assets that would be superior to the rights of stockholders until the principal, accrued and unpaid interest, and any premium or make-whole has been paid. In addition, if we borrow funds and/or issue debt securities through a subsidiary, the lenders and/or holders of those debt securities would have a right to payment that would be effectively senior to the Company's equity ownership in the subsidiary, which would adversely affect the rights of holders of both the Company's equity securities and its debt and debt securities.

Interest in any newly-issued debt securities and/or newly-incurred borrowings would increase our operating costs and increase our net loss, and these impacts may be material. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common shares could be materially and adversely affected. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could result in a material adverse effect on our business, operating results, financial condition and prospects.

Changes in tax legislation could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service ("IRS") and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Anti-takeover provisions in our 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.

Our fifth amended and restated certificate of incorporation and amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of th board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken a meeting of our stockholders;
- a requirement that special meetings of the stockholders may be called only by the board of directors acting pursu to a resolution approved by the affirmative vote of a majority of the directors then in office, and special meetings stockholders may not be called by any other person or persons;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

- a requirement that no member of our board of directors may be removed from office by our stockholders except cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action and not less than two-thirds (2/3) of all outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

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

Our bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

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

The Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of such lawsuits against us and our directors, officers and employees even though an

action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

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

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the COVID-19 pandemic caused significant volatility and uncertainty in U.S. and international markets. See "Risks Related to the Development of our Targeted Oncology and Other Programs and Product Candidates—The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates." Inflation rates, particularly in the United States, have increased recently to levels not seen in years. Increased inflation may result in increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks, which may impact our ability to raise additional capital in the future. Potential instability throughout the banking industry and their potential near- and long-term effects on the biotechnology industry and its participants such as our vendors, suppliers, and investors, may also adversely affect our operations and stock price. In addition, U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions, and the start of the military conflict between Russia and Ukraine. Ukraine, and evolving events in Israel and Gaza. On February 24, 2022, a full-scale military invasion of Ukraine by Russian troops began. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain disruptions. Various of Russia's actions have led to sanctions and other penalties being levied by the United States, Australia, the European Union, and other countries, as well as other public and private actors and companies, against Russia and certain other geographic

areas, including agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication payment system and restrictions on imports of Russian oil, liquified natural gas and coal. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could disrupt or otherwise adversely impact our operations and the operations of third parties upon which we rely, as well as the global economy and financial markets, and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. Related sanctions, export controls or other actions that may 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 which we conduct business. A severe or prolonged economic downturn, inflationary environment, rising interest rates, or political unrest could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to

delay making payments for our services. The extent and duration of the military action, sanctions, and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Quarterly Report on Form 10-Q and the documents incorporated by reference herein.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the

reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of 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, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but 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 comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are an "emerging growth company" as defined in the JOBS Act and a "smaller reporting company" as defined in the Exchange Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) December 31, 2026; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act 2002, or Section 404;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of executive officers.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the available exemptions available to us so long as we qualify as an "emerging growth company." We have taken advantage of reduced reporting burdens in this Quarterly Report on Form 10-Q. In particular, we have provided only two years of audited financial statements and

have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. GAAP or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

As a public company, and particularly after we are no longer an "emerging growth company" or a "smaller reporting company," we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company or a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that

controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In additional, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and

forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

The market price of our common stock may be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds from our Public Offering of Common Stock

On March 30, 2021, we closed our IPO, in which we issued and sold 8,984,375 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,171,875 additional shares of common stock, at a public offering price of $16.00 per share. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333- 253919), which was declared effective by the SEC on March 25, 2021 (the "Prospectus"). Jefferies LLC, Cowen and Company, LLC, Credit Suisse Securities (USA) LLC, and William Blair & Company, L.L.C., acted as joint book-running managers for the offering. The aggregate gross proceeds to us from our IPO, inclusive of the over-allotment exercise, were $143.8 million.

The aggregate net proceeds to us from the IPO, inclusive of the over-allotment exercise, was approximately $131.3 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

There has been no material change in the planned use of IPO proceeds from that described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on March 26, 2021.

(c) Issuer Purchases of Equity Securities

On June 13, 2023, the Company entered into a definitive stock purchase agreement with a stockholder, as part of a privately negotiated transaction, to repurchase 97,500 shares of common stock held by them for an aggregate purchase price of $0.7 million, or $6.80 per share. This repurchase was completed on June 26, 2023.

Repurchased shares are held as treasury stock at cost until they are retired or re-issued. The shares were retired on June 29, 2023.

Period	Total Number of Shares Purchased(1)	Average Price Paid Per Share	Total Number of Shares Purchased Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased under the Plans or Programs
April 1, 2023 to April 30, 2023	—	$ —	—	—
May 1, 2023 to May 31, 2023	—	$ —	—	—
June 1, 2023 to June 30, 2023	97,500	$ 6.80	—	—
Total	97,500	$ 6.80	—	—

(1)The shares were not re-acquired pursuant to any repurchase plan or program. The Company re-acquired the shares of common stock pursuant to a definitive stock purchase agreement with a stockholder. None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.3 2.1#	Agreement and Plan of Merger, dated August 4, 2023, by and among Ikena Oncology, Inc., Portsmouth Merger Sub I, Inc., Portsmouth Merger Sub II, LLC, Pionyr Immunotherapeutics, Inc. and Fortis Advisors LLC, as securityholder agent (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on August 7, 2023).
3.1	Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3,1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on August 7, 2023).
3.2	Fifth Amended and Restated Certificate of Incorporation of Ikena Oncology, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on March 30, 2021).
3.5 3.3	Amended and Restated Bylaws of Ikena Oncology, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on March 30, 2021).

4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-253919) filed with the SEC on March 22, 2021).
4.2	Fourth Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 18, 2020 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-253919) filed with the SEC on March 5, 2021)
4.3	Form of Senior Indenture between Registrant and one or more trustees to be named (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-3 (File No. 333-264517) filed with the SEC on April 27, 2022)
4.4	Form of Subordinated Indenture between Registrant and one or more trustees to be named, (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-3 (File No. 333-264517) filed with the SEC on April 27, 2022)
10.1	Contingent Value Rights Agreement, dated August 4, 2023, by and between Ikena Oncology, Inc. and Computershare Trust Company N.A, as rights agent (incorporated by reference to Exhibit 3,1 to the Registrant's Current Report on Form 8-K (File No. 001-40287) filed with the SEC on August 7, 2023).
31.1*	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.
31.2*	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.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance 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

* Filed herewith.

+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

73 # Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(2). Such excluded information is not material and the Registrant customarily and actually treats as private or confidential.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IKENA ONCOLOGY, INC.

Date: August 10, 2023 November 9, 2023

By: /s/ Mark Manfredi

Mark Manfredi

Chief Executive Officer

(Principal Executive Officer)

Date: August 10, 2023 November 9, 2023

By: /s/ Jotin Marango

Jotin Marango

Chief Financial Officer and Head of Corporate Development

(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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, Mark Manfredi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ikena Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a materi fact necessary to make the statements made, in light of the circumstances under which such statements were made, n 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 all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the per 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in w this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting ar the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report ou conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covere this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred durin the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) th 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 registrant's internal control over financial reporting.

Date: August 10, 2023 November 9, 2023

By: /s/ Mark Manfredi

Mark Manfredi

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

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, Jotin Marango, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ikena Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a materi fact necessary to make the statements made, in light of the circumstances under which such statements were made, n 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 all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the per 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in w this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting ar the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report ou conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covere this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred durin the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) th 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 registrant's internal control over financial reporting.

Date: August 10, 2023 November 9, 2023

By: /s/ Jotin Marango

Jotin Marango

Chief Financial Officer and Head of Corporate Development

(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with this Quarterly Report on Form 10-Q for the period ending June 30, 2023 September 30, 2023 of Ikena Oncology, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; a

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results operations of the Company.

Date: August 10, 2023 November 9, 2023

By: /s/ Mark Manfredi

Mark Manfredi, Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

By: /s/ Jotin Marango

Jotin Marango

Chief Financial Officer and Head of Corporate Development

(Principal Financial Officer and Principal Accounting Officer)

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