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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

o **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: 001-38560

AADI BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**61-1547850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
17383 Sunset Boulevard Suite A250 **Pacific Palisades, California**	**90272**
(Address of principal executive offices)	**(Zip Code)**

(424) 744-8055
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value per share	AADI	The Nasdaq Stock Market LLC

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 x No o

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 x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	x

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. x

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

As of November 4, 2022, the registrant had 24,395,117 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

AADI BIOSCIENCE, INC.

Condensed Consolidated Balance Sheets
(Amounts in thousands, except share data and par value)
(Unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	**$ 134,815**	$ 148,989
Short-term investments	**48,192**	—
Accounts receivable, net	**2,261**	—
Inventory	**734**	—
Prepaid expenses and other current assets	**3,861**	2,283
Total current assets	**189,863**	151,272
Property and equipment, net	**457**	57
Operating lease right-of-use assets	**1,573**	557
Intangible asset, net	**—**	3,811
Other assets	**2,210**	2,213
Total assets	**$ 194,103**	$ 157,910
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 3,920**	$ 6,439
Accrued liabilities	**13,597**	8,703
Operating lease liabilities, current portion	**374**	131
Total current liabilities	**17,891**	15,273
Operating lease liabilities, net of current portion	**1,347**	474
Due to licensor (Note 8)	**5,757**	5,757
Total liabilities	**24,995**	21,504
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2022 and December 31, 2021	**—**	—
Common stock, $0.0001 par value; 300,000,000 shares authorized; 24,395,117 and 20,894,695 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	**2**	2
Additional paid-in capital	**358,490**	279,089
Accumulated other comprehensive loss	**(99)**	—
Accumulated deficit	**(189,285)**	(142,685)
Total stockholders' equity	**169,108**	136,406
Total liabilities and stockholders' equity	**$ 194,103**	$ 157,910

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

AADI BIOSCIENCE, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Product sales, net	**$ 4,245**	$ —	**$ 9,989**	$ —
Grant revenue	**—**	—	**—**	120
Total revenue	**4,245**	—	**9,989**	120
Operating expenses				
Selling, general and administrative	**9,915**	7,401	**29,069**	8,793
Research and development	**8,773**	5,754	**23,292**	12,443
Cost of goods sold	**593**	—	**1,113**	—
Impairment of acquired contract intangible asset	**—**	74,156	**3,724**	74,156
Total operating expenses	**19,281**	87,311	**57,198**	95,392
Loss from operations	**(15,036)**	(87,311)	**(47,209)**	(95,272)
Other income (expense)				
Change in fair value of convertible promissory notes	**—**	380	**—**	1,585
Gain upon extinguishment of debt	**—**	—	**—**	196
Interest income	**620**	—	**791**	1
Interest expense	**(58)**	(157)	**(173)**	(608)
Total other income, net	**562**	223	**618**	1,174
Loss before income tax expense	**(14,474)**	(87,088)	**(46,591)**	(94,098)
Income tax expense	**—**	—	**(9)**	(2)
Net loss	**(14,474)**	(87,088)	**(46,600)**	(94,100)
Other comprehensive loss:				
Change in unrealized loss on short-term investments	**(99)**	—	**(99)**	—
Comprehensive loss	**$ (14,573)**	$ (87,088)	**$ (46,699)**	$ (94,100)
Net loss per share attributable to common stockholders, basic and diluted	**$ (0.68)**	$ (9.17)	**$ (2.21)**	$ (19.37)
Weighted average number of common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	**21,269,163**	9,510,379	**21,052,786**	4,890,556

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(Amounts in thousands, including share amounts)
(Unaudited)

	For the Three and Nine Months Ended September 30, 2022					
	Stockholders' Equity					
	Common Stock					
	Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balance at January 1, 2022	20,895	$ 2	$ 279,089	$ —	$ (142,685)	$ 136,406
Share-based compensation expense	—	—	1,781	—	—	1,781
Issuance of common stock upon exercise of warrants	7	—	54	—	—	54
Issuance of common stock upon exercise of stock options	40	—	244	—	—	244
Net loss	—	—	—	—	(13,857)	(13,857)
Balance at March 31, 2022	20,942	2	281,168	—	(156,542)	124,628
Share-based compensation expense	—	—	2,235	—	—	2,235
Issuance of common stock upon exercise of stock options	75	—	136	—	—	136
Net loss	—	—	—	—	(18,269)	(18,269)
Balance at June 30, 2022	21,017	2	283,539	—	(174,811)	108,730
Share-based compensation expense	**—**	**—**	**2,757**	**—**	**—**	**2,757**
Issuance of common stock upon exercise of stock options	**5**	**—**	**16**	**—**	**—**	**16**
Private placement, net of transaction costs	**3,373**	—	**72,178**	—	—	**72,178**
Other comprehensive loss	—	—	—	**(99)**	—	**(99)**
Net loss	**—**	**—**	**—**	**—**	**(14,474)**	**(14,474)**
Balance at September 30, 2022	**24,395**	**$ 2**	**$ 358,490**	**$ (99)**	**$ (189,285)**	**$ 169,108**

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Stockholders' Equity (Deficit) (continued)
(Amounts in thousands, including share amounts)
(Unaudited)

	For the Three and Nine Months Ended September 30, 2021								
	Series Seed Preferred Stock		Series A Preferred Stock		Stockholders' Equity (Deficit)				
					Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Par Value			
Balance at January 1, 2021	734	$ —	7,212	$ 1	2,542	$ 1	$ 20,161	$ (32,595)	$ (12,432)
Share-based compensation expense	—	—	—	—	—	—	36	—	36
Net loss	—	—	—	—	—	—	—	(5,476)	(5,476)
Balance at March 31, 2021	734	—	7,212	1	2,542	1	20,197	(38,071)	(17,872)
Share-based compensation expense	—	—	—	—	—	—	39	—	39
Net loss	—	—	—	—	—	—	—	(1,536)	(1,536)
Balance at June 30, 2021	734	$ —	7,212	1	2,542	1	20,236	(39,607)	(19,369)
Issuance of common stock upon exercise of stock options	—	—	—	—	61	—	745	—	745
Issuance of common stock to PIPE Investors, net of issuance costs	—	—	—	—	11,853	1	145,383	—	145,384
Issuance of common stock to former stockholders of Aerpio upon Merger	—	—	—	—	3,209	—	105,888	—	105,888
Conversion of convertible promissory note into common stock upon Merger	—	—	—	—	698	—	9,130	—	9,130
Conversion of convertible preferred stock into common stock upon Merger	(734)	—	(7,212)	(1)	2,520	—	—	—	(1)
Share-based compensation expense	—	—	—	—	—	—	648	—	648
Cumulative dividends paid on Series A preferred stock	—	—	—	—	—	—	(4,412)	—	(4,412)
Net loss	—	—	—	—	—	—	—	(87,088)	(87,088)
Balance at September 30, 2021	—	$ —	—	$ —	20,883	$ 2	$ 277,618	$ (126,695)	$ 150,925

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands)

(Unaudited)

	Nine Months Ended September 30, 2022	2021
Cash flows from operating activities:		
Net loss	**$ (46,600)**	$ (94,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of acquired contract intangible asset	**3,724**	74,156
Share-based compensation expense	**6,773**	723
Amortization of premiums and discounts on short-term investments, net	**(149)**	—
Change in fair value of convertible promissory notes	**—**	(1,585)
Non-cash interest expense	**—**	584
Gain upon extinguishment of debt	**—**	(196)
Non-cash lease expense	**270**	133
Depreciation and amortization expense	**113**	33
Changes in operating assets and liabilities:		
Accounts receivable	**(2,261)**	14,149
Inventory	**(734)**	—
Prepaid expenses and other current assets	**(1,578)**	(526)
Other non-current assets	**365**	430
Operating lease liability	**(170)**	(121)
Accounts payable and accrued liabilities	**1,917**	4,860
Other liabilities	**—**	(8,535)
Net cash used in operating activities	**(38,330)**	(9,995)
Cash flows from investing activities:		
Purchases of property and equipment	**(366)**	—
Purchase of short-term investments	**(48,141)**	—
Cash acquired in connection with the Merger	**—**	29,700
Transaction expenses related to the Merger	**—**	(4,501)
Net cash (used in) provided by investing activities	**(48,507)**	25,199
Cash flows from financing activities:		
Proceeds from sale of common stock and prefunded warrants	**72,500**	—
Issuance of common stock upon exercise of stock options	**396**	745
Issuance of common stock to PIPE Investors	**—**	155,000
Costs incurred in connection with issuance of common stock	**—**	(9,617)
Dividends paid	**—**	(4,412)
Issuance of common stock upon exercise of warrants	**54**	—
Deferred offering costs paid for financing	**(223)**	—
Net cash provided by financing activities	**72,727**	141,716
Net (decrease) increase in cash, cash equivalents and restricted cash	**(14,110)**	156,920
Cash, cash equivalents and restricted cash at beginning of year	**148,989**	4,455
Cash, cash equivalents and restricted cash, end of period	**$ 134,879**	$ 161,375

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Cash Flows (continued)

(Amounts in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2022	**2021**
Supplemental disclosure of cash flow information:		
Interest paid during the period	**$ 173**	$ —
Taxes paid during the period	**$ 9**	$ —
Issuance of common stock upon Merger	**$ —**	$ 105,888
Conversion of promissory note into common stock upon Merger	**$ —**	$ 9,130
Supplemental disclosure of non-cash activities:		
Costs incurred in connection with Private Placement included in accounts payable	**$ 322**	$ —
Deferred transaction costs included in accounts payable and accrued liabilities	**$ 75**	$ —
Accrued property and equipment	**$ 60**	$ —
Operating lease liability arising from obtaining right-of-use asset	**$ 1,210**	$ 610

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of Organization and Operations

Aadi Bioscience, Inc. (together with its subsidiaries, the "Company" or "Aadi") is a biopharmaceutical company focused on developing and commercializing precision therapies for genetically defined cancers with alterations in mTOR pathway genes. Aadi's lead drug product, FYARRO®, is a form of sirolimus bound to albumin. Sirolimus is a potent inhibitor of the mTOR biological pathway, the activation of which pathway can promote tumor growth, and inhibits downstream signaling from mTOR. In November 2021, the U.S. Food and Drug Administration (the "FDA") approved FYARRO sirolimus protein-bound particles for injectable suspension (albumin-bound) for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor ("PEComa"). On February 22, 2022, Aadi launched FYARRO in the United States for treatment of advanced malignant PEComa. FYARRO is licensed to Aadi by Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, now Bristol Myers Squibb Company ("Celgene"), for all therapeutic areas including oncology, cardiovascular, and metabolic related diseases.

The Company's historical operations have consisted principally of performing research and development activities and raising capital. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding before sustainable revenues and profit from operations are achieved.

Merger with Aerpio Pharmaceuticals, Inc. and Name Change

On May 16, 2021, the Company, then operating as Aerpio Pharmaceuticals, Inc. ("Aerpio"), entered into the Agreement and Plan of Merger ("Merger Agreement") with Aspen Merger Subsidiary, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Aerpio ("Merger Sub") and Aadi Subsidiary, Inc. (formerly known as Aadi Bioscience, Inc. ("Private Aadi")).

Pursuant to the terms set forth in the Merger Agreement and effective August 26, 2021 (the "Effective Time"): (i) Merger Sub merged with and into Private Aadi, with Private Aadi surviving as a wholly owned subsidiary of Aerpio (the "Merger"), (ii) Aerpio changed its name to Aadi Bioscience, Inc. in connection with and immediately prior to the Effective Time, and (iii) Aerpio effected a 15:1 reverse stock split of the Aerpio common stock ("Reverse Stock Split") immediately prior to the Effective Time. At the Effective Time, each share of Private Aadi common stock outstanding immediately prior to the Effective Time, including the shares of Private Aadi common stock issuable upon the conversion of all shares of preferred stock and convertible promissory notes immediately prior to the closing of the Merger, were converted into the right to receive shares of the Company's common stock based on an exchange ratio of 0.3172 (the "Exchange Ratio"), after taking into account the Reverse Stock Split.

Pursuant to the Merger Agreement, Aerpio assumed all of the outstanding and unexercised options to purchase shares of Private Aadi capital stock under the Private Aadi Amended and Restated 2014 Equity Incentive Plan (the "Private Aadi Plan"), and, in connection with the Merger, such options were converted into options to purchase shares of the Company's common stock based on the Exchange Ratio. At the closing of the Merger at the Effective Time, the Company issued an aggregate of 5,776,660 shares of common stock to holders of Private Aadi common stock, including in respect of shares of Private Aadi common stock issued upon the conversion of all shares of preferred stock and convertible promissory notes outstanding immediately prior to the Effective Time.

The Merger has been accounted for using the reverse asset acquisition method under U.S. generally accepted accounting principles ("GAAP"). For accounting purposes, Private Aadi is considered to have acquired the Company and the Merger has been accounted for as a reverse asset acquisition. The estimated fair value of total consideration given was $110.4 million based on 3,208,718 shares of common stock at $33.00 per share, after taking into account the Reverse Stock Split, outstanding immediately prior to the Effective Time, plus Private Aadi's transaction costs. Private Aadi is considered the accounting acquirer even though the Company issued the common stock in the Merger based on the terms of the Merger Agreement and other factors including: (i) following the Merger, the stockholders of Private Aadi collectively owned a substantial portion of the voting rights of the Company; (ii) three (3) of seven (7) members of the board of directors of the Company post-Merger were composed of directors designated by Private Aadi under the terms of the Merger Agreement, and one (1) member of the board of directors of the Company post-Merger was a director mutually designated by Private Aadi and Aerpio; (iii) existing members of Private Aadi's management became the management of the Company post-Merger; (iv) the PIPE Investors (as defined below) consist of individuals and funds, and for purpose of this analysis, while they owned approximately 55.6% on a fully-diluted basis, as of immediately following the Merger (and after giving effect to the PIPE Financing), no one individual or fund held more shares than the holders of Private Aadi collectively owned immediately following the Merger and they are not considered to be a single voting group; and (v) following the Merger, the Company is named "Aadi Bioscience, Inc." and headquartered in Pacific Palisades, California, and all ongoing operations of the Company are those of Private Aadi. To determine the accounting for this transaction

under GAAP, a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. Upon closing of the Merger, substantially all of the fair value is concentrated in cash, working capital and a long-lived contract intangible asset. As such, the acquisition was treated as an asset acquisition. The net assets of Aerpio have been recorded at their relative fair value in the consolidated financial statements of the Company and the reported operating results prior to the Merger will be those of Private Aadi.

In connection with the closing of the Merger, Private Aadi's board of directors declared a 4% cumulative dividend on its preferred stock of $4.4 million which was paid at the Effective Time.

Contingent Value Rights and Contingent Value Rights Agreement

In connection with the Merger, the Company entered into a Contingent Value Rights Agreement, dated as of August 26, 2021 (the "CVR Agreement"), with a legacy director of the Company, as Holder Representative (as defined in the CVR Agreement), and American Stock Transfer & Trust Company, LLC, as Rights Agent (as defined in the CVR Agreement), in accordance with the terms of the Merger Agreement. The CVR Agreement entitled each holder of Aerpio common stock as of immediately prior to the closing of the Merger (each, a "CVR Holder") to receive one contingent value right ("CVR") for each outstanding share of the Company common stock held by such CVR Holder as of immediately prior to the closing of the Merger, each representing the right to receive certain net proceeds, if any, derived from the CVR completed during a CVR Payment Period, which means successive six-month periods, prior to the expiration of the CVR Term (as defined in the CVR Agreement), with any potential payment obligations continuing until the earlier of (a) the 20-year anniversary of the Effective Time and (b) the time at which the license agreement dated June 24, 2018, as amended (the "Gossamer License Agreement") with Gossamer Bio, Inc. ("Gossamer"), the underlying basis for the CVR, has expired or been terminated.

On April 25, 2022, the Company received a formal notice of termination from Gossamer for the Gossamer License Agreement (the "Notice of Termination"), that related to Gossamer's GB004 product candidate, a legacy product candidate of the Company's predecessor, Aerpio, after Gossamer announced that its Phase 2 SHIFT-UC clinical trial studying GB004 in patients with mild-to-moderate active ulcerative colitis did not meet the primary or secondary endpoints at week 12 and the study was being terminated for lack of treatment benefit. The Gossamer License Agreement terminated effective July 24, 2022.

Based on the Notice of Termination, the Company fully impaired the Gossamer License Agreement intangible asset during the nine months ended September 30, 2022. In connection with the termination of the Gossamer License Agreement, the CVR Agreement, pursuant to which the CVRs were issued to legacy holders of common stock of Aerpio immediately prior to the Merger, automatically terminated in accordance with its terms and the CVRs were automatically cancelled and forfeited without any consideration or payment, in each case effective July 24, 2022.

PIPE Financing and Subscription Agreement

On May 16, 2021, the Company entered into a subscription agreement ("Subscription Agreement") with certain investors (the "PIPE Investors"), pursuant to which it would sell shares of its Common Stock concurrently with the closing of the Merger (the "PIPE Financing"). At the closing of the PIPE Financing, the Company entered into a Registration Rights Agreement, dated August 26, 2021 ("Registration Rights Agreement"), with the PIPE Investors. The PIPE Investors purchased an aggregate of 11,852,862 shares of common stock of the Company (the "PIPE Shares") for an aggregate purchase price of $155.0 million pursuant to the Subscription Agreement ("PIPE Financing"). The aggregate net proceeds for the issuance and sale of the PIPE Shares were $145.4 million, after deducting certain expenses incurred that were direct and incremental to the issuance of the PIPE Shares.

Immediately following the Effective Time, and after giving effect to the Reverse Stock Split and the PIPE Financing, there were approximately 20.8 million shares of common stock of the Company outstanding. Immediately following the Effective Time and after giving effect to the Reverse Stock Split and the PIPE Financing: (i) the Private Aadi stockholders owned approximately 29.2% of the outstanding shares of common stock; (ii) Aerpio's stockholders immediately prior to the Merger, whose shares of common stock, as adjusted for the Reverse Stock Split, remain outstanding after the Merger, owned approximately 15.2% of the outstanding shares of common stock; and (iii) the PIPE Investors owned approximately 55.6% of the outstanding shares of common stock, in each case as calculated on a fully-diluted basis.

Private Placement Financing

On September 22, 2022, the Company entered into a securities purchase agreement ("Purchase Agreement") with certain investors ("Private Placement Investors") for a private placement of shares of common stock and pre-funded warrants to purchase shares of common stock (the "Private Placement Financing"). Upon the closing of the Private Placement Financing on September 26, 2022, the Company sold (i) 3,373,526 shares of its common stock at a purchase price of $12.50 per share, and (ii) 2,426,493 pre-funded warrants (the "Pre-Funded Warrants") to purchase shares of common stock

at a purchase price of $12.4999 per pre-funded warrant. The Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. The holders of Pre-Funded Warrants may not exercise a Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise; provided, that the holders of Pre-Funded Warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days' prior notice to the Company. The aggregate net proceeds for the Private Placement Financing were $72.2 million after deducting certain expenses incurred that were direct and incremental to the issuance of the shares of $0.3 million.

On September 26, 2022, the Company and the Private Placement Investors entered into a Registration Rights Agreement, (the "Private Placement Registration Rights Agreement"), providing for the registration for resale of the securities sold under the Purchase Agreement, including the shares issuable upon the exercise of the Pre-Funded Warrants, that are not then registered on an effective registration statement, pursuant to a registration statement filed with the Securities and Exchange Commission (the "SEC"). The Company filed a resale registration statement with the SEC on October 26, 2022.

The Company has granted the Private Placement Investors customary indemnification rights in connection with the Private Placement Registration Rights Agreement. The Purchasers have also granted the Company customary indemnification rights in connection with the Private Placement Registration Rights Agreement.

Liquidity

Since inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations and has only recently begun to realize revenues from its planned principal operations commencing with the commercial sale of FYARRO.

The Company has experienced net losses since its inception and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of $189.3 million as of September 30, 2022 and net loss of $14.5 million and $46.6 million for the three and nine months ended September 30, 2022, respectively. To date, these operating losses have been funded primarily from outside sources of invested capital through the issuance of convertible promissory notes, grant funding, the sale of securities, and proceeds from license agreements.

The Company had cash, cash equivalents and short-term investments of $183.0 million at September 30, 2022. Management believes the Company's current cash, cash equivalents and short-term investments will provide sufficient funds to enable the Company to meet its obligations for at least twelve months from the filing date of this report.

On March 17, 2022, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company may offer and sell, from time to time at the Company's sole discretion, shares of its common stock having an aggregate offering prices of up to $75.0 million through Cowen as its sales agent. As of September 30, 2022, no shares of common stock had been sold under this Sales Agreement.

COVID-19

In late 2019, a strain of coronavirus was reported in Wuhan, China and began to spread globally, including to the United States and Europe, in the following months. The World Health Organization has declared COVID-19 to be a global pandemic. The full impact of the COVID-19 pandemic is inherently uncertain at the time of this report. The COVID-19 pandemic has resulted in travel restrictions and, in some cases, prohibitions of non-essential activities, disruption and shutdown of businesses, and greater uncertainty in global financial markets. As COVID-19 has spread, it has significantly impacted the health and economic environment around the world. Aadi's clinical trials have been, and may continue to be, affected by the closure of offices, or country borders, among other measures being put in place around the world. Restrictions on the ability to travel and conduct face-to-face meetings, as well as constraints surrounding hospital resources, infrastructure, staff and other resources, can also make it more difficult to enroll new patients in ongoing or planned clinical trials. Any of these circumstances will potentially have a negative impact on the Company's financial results and the timing of its clinical trials.

The COVID-19 pandemic has caused the Company to modify business practices (including but not limited to curtailing or modifying employee travel and participation in meetings, events, and conferences, and curtailing or modifying its clinical trials), and may take further actions as may be required by government authorities or that are determined to be in the best interests of the Company's employees, patients, and business partners.

The extent of the impact of the COVID-19 pandemic on Aadi's future liquidity and operational performance will depend on certain developments, including the duration and spread of further outbreaks, the availability, acceptance and effectiveness of vaccines, the impact on the Company's clinical trials, patients, and collaboration partners, and the effect on its suppliers.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements, and the related disclosures, have been prepared in accordance with GAAP and SEC regulations and, in the opinion of management include all adjustments necessary for a fair presentation of the results of operations, financial position, changes in stockholders' equity and cash flows for each period presented. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). All adjustments are of a normal recurring nature. The Company's condensed consolidated financial statements are stated in U.S. dollars.

Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted. Accordingly, the accompanying unaudited interim financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2021, which are included in the Company's Annual Report on Form 10-K filed with the SEC on March 17, 2022.

On August 26, 2021, when the Company closed the Merger, all outstanding shares of common stock along with preferred stock of Private Aadi were exchanged for new shares of common stock of the Company and the approximately 8.1 million shares of Private Aadi capital stock held by stockholders of Private Aadi immediately prior to the Merger were exchanged for approximately 2.5 million shares of common stock of the Company based on the Exchange Ratio. The authorized number of shares of common stock was not reduced and remains at 300.0 million. The par value of the Company's common stock remains unchanged at $0.0001 per share.

Also on August 26, 2021, and immediately prior to the closing of the Merger, the Company effected the Reverse Stock Split. Accordingly, all share and per share amounts for the period presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split. Unless otherwise noted, all references to shares of the Company's common stock and per share amounts have also been adjusted to reflect the Exchange Ratio.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on short-term investments. Comprehensive loss has been reflected in the statements of operations and comprehensive loss for all periods presented.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company has identified its Chief Executive Officer as the chief operating decision maker and the Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing proprietary therapeutics. All the assets and operations of the Company's sole operating and reportable segment are located in the United States.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes. In the opinion of management, all adjustments that are considered necessary for fair presentation have been included. The most significant estimates in the Company's condensed consolidated financial statements relate to fair value of the intangible asset, fair value of the convertible promissory notes, gross-to-net accruals, stock-based compensation expense and accrued research and development costs. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents and certain investments in money market funds. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has not experienced any losses on deposits since inception.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid marketable securities purchased with original maturities of three months or less at the time of purchase date to be cash equivalents. As of September 30, 2022 and December 31, 2021, cash and cash equivalents included money market investments totaling $126.1 million and $140.0 million, respectively. Restricted cash consists of a letter of credit secured by restricted cash in connection with one of the Company's office leases described in Note 7, and is included in other assets on the condensed consolidated balance sheet. The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated statements of cash flows (amounts in thousands):

	September 30, 2022	December 31, 2021
Cash and cash equivalents	**$ 134,815**	$ 148,989
Restricted cash, non-current	**64**	—
Total cash, cash equivalents and restricted cash	**$ 134,879**	$ 148,989

Short-Term Investments

The Company’s short-term investments consist of various types of securities, including United States government, commercial paper and corporate debt securities. The Company classifies its short-term investments as available-for-sale and records such assets at estimated fair value in the condensed consolidated balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the condensed consolidated statements of operations and comprehensive loss and as a separate component of stockholders’ equity. Dividend and interest income are recognized when earned. The Company classifies short-term investments with remaining maturities greater than one year as current assets because such short-term investments are available to fund the Company’s current operations. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of the investment sold. There were no realized gains and losses during any of the periods presented. The Company may sell these securities at any time for use in current operations.

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the unrealized loss is other-than-temporary. When the Company determines that a decline in the fair value below its cost basis is other-than-temporary, the Company recognizes an impairment loss in the period in which the other-than-temporary decline occurred. There have been no other-than-temporary impairments recognized during any of the periods presented. See Note 4 (Short-Term investments) for further information

Fair Value Option

The Company has elected the fair value option to account for its convertible promissory notes issued. The Company records these convertible promissory notes at fair value with changes in fair value recorded in the statements of operations and comprehensive loss. As of September 30, 2022, there were no convertible notes outstanding as they were converted to shares of Private Aadi common stock immediately prior to the closing of the Merger.

Fair Value of Financial Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs, such as quoted prices in active markets

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions which reflect those that a market participant would use

Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

In determining the fair value of its financial instruments, the Company considers the source of observable market data inputs, liquidity of the instrument, the credit risk of the counterparty to the contract, and its risk of nonperformance. In the case fair value is not observable, for the items subject to fair value measurements, the Company applies valuation techniques deemed the most appropriate under the GAAP guidance based on the nature of the assets and liabilities being measured.

The carrying amounts of cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, and accounts payable are reasonable estimates of their fair value because of the short maturity of these items.

Accounts Receivable, Net

Accounts receivable are recorded net of customer allowances for chargebacks and allowance for doubtful accounts. Allowance for chargebacks is based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. As of September 30, 2022, $0.1 million of customer allowances for chargebacks was recorded. No allowances were recorded as of December 31, 2021.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value. The Company uses actual costing methodology determined on a first-in, first-out method. The Company capitalizes inventory costs associated with its products based upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of FYARRO, all costs related to the manufacturing of FYARRO were charged to research and development expense in the period incurred, therefore the inventory balance was zero at December 31, 2021. Details of inventory are presented as follows (amounts in thousands).

	September 30, 2022
Raw materials	**$ 19**
Work in process	**513**
Finished goods	**202**
Total	**$ 734**

Property and Equipment, Net

Property and equipment, consisting of computers, furniture and fixtures, office equipment, construction in process and leasehold improvements are stated at cost, less accumulated depreciation. Property and equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Such costs are periodically reviewed for recoverability when impairment indicators are present.

Intangible Asset, Net

The Company's intangible asset consisted of a single asset, the Gossamer License Agreement, assumed in the Merger. The intangible asset was stated at fair value and amortized using the straight-line method over its estimated useful life of 14.3 years. During the three and nine months ended September 30, 2021, the acquired intangible asset was reduced to the contract intangible asset to its estimated fair value of $3.9 million at the Effective Time. During the nine months ended September 30, 2022, the intangible asset's fair value was reduced to zero based on the termination of the Gossamer License Agreement effective July 24, 2022 (see Note 5).

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property, equipment, and the intangible asset for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. An impairment was recorded for the long-lived intangible asset during the nine months ended September 30, 2022 based on the termination of the Gossamer License Agreement effective July 24, 2022 (see Note 5).

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in

exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company does not recognize assets or liabilities for leases with lease terms of less than 12 months.

The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: (i) the lease has a purchase option that is reasonably certain of being exercised, (ii) the present value of the future cash flows is substantially all of the fair market value of the underlying asset, (iii) the lease term is for a significant portion of the remaining economic life of the underlying asset, (iv) the title to the underlying asset transfers at the end of the lease term, or (v) if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding right-of-use assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term.

Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. As the Company's leases do not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. For finance leases, depreciation expense is recognized for the leased asset acquired and interest expense is recognized related to the portion of the financing in the statements of operations and comprehensive loss. For operating leases, lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expense in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to not separate between lease and non-lease components.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of September 30, 2022 and December 31, 2021.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, Revenue from Contracts with Customer ("Topic 606"), the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Net Sales

FYARRO was approved by the FDA in November 2021. On February 22, 2022, the Company launched sales of FYARRO to specialty distributors ("SD"s) and a specialty pharmacy ("SP"). The Company recognizes product sales when the SDs and SP obtain control of the product. Product sales are recorded at the net sales price, which includes provisions for the following allowances which are reflected either as a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

Distribution Fees: Distribution fees include distribution service fees paid to the SDs and SP based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"). Distribution fees are recorded as an offset to product sales based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowance for rebates includes mandated discounts under the Medicaid Drug Rebate Program and TRICARE program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. The Company's estimates for expected utilization of rebates are based on utilization data received from the SDs and SP since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs and SP at a discounted price. The SDs and SP charge back to the Company the difference between the price initially paid by the SDs and SP and the discounted price paid to the SDs and SP by these entities. If actual future chargebacks vary from these estimates, the Company may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirement. Co-payment assistance is accrued at the time of product sale to SDs and SP based on estimated patient participation and average co-pay benefit to be paid per a claim. The Company estimated amounts are compared to actual program participation and co-pay amounts paid using data provided by third-party administrators. If actual amounts differ from the original estimates the assumptions being applied are updated and adjustment for prior period accruals will be adjusted in the current period.

Product Returns: Consistent with industry practice, the Company offers the SDs and SP limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SDs and SP and has the ability to control the amount of product that is sold to the SDs and SP the Company's estimate of future potential product returns is based on the on-hand channel inventory data and sell-through data obtained from the SDs and SP. In arriving at its estimate, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

The total amount deducted from gross product sales for the allowances described above for the three and nine months ended September 30, 2022 was $0.8 million and $1.8 million, respectively.

Grant Revenue

The Company's grant revenues are derived from federal grants with the FDA. The Company has determined that the government agencies providing grants to the Company are not customers. Grant revenue is recognized when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received. The Company recognizes grant revenues as reimbursable grant costs are incurred. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

With respect to grant revenue derived from reimbursement of direct out-of-pocket expenses for research costs associated with federal contracts, where the Company acts as principal with discretion to choose suppliers, bears credit risk, and performs part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

Revenue Under License Agreement

The Company generates revenues from payments received under a license agreement. Under such license agreement, the Company recognizes revenue when it transfers promised goods or services to partners in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with partners, the Company performs the following five steps: (i) identifies the promised goods or services in the contract; (ii) identifies the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determines the transaction price, including the constraint on variable consideration; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the Company satisfies the performance obligations.

For revenue from such license agreement, the Company generally collects an upfront license payment from the license partner and is also entitled to receive event-based payments subject to the license partner's achievement of specified

development, regulatory and sales-based milestones. In addition, the Company is generally entitled to royalties if products under the license agreement are commercialized.

Transaction price for a contract represents the amount to which the Company is entitled in exchange for providing goods and services to the partner. Transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. Apart from the upfront license payment, all other fees the Company may earn under such license agreements are subject to significant uncertainties of product development. Achievement of many of the event-based development and regulatory milestones may not be probable until such milestones are actually achieved. This generally relates to milestones such as obtaining regulatory approvals and successful completion of clinical trials. With respect to other development milestones, e.g. dosing of a first patient in a clinical trial, achievement could be considered probable prior to its actual occurrence, based on the progress towards commencement of the trial. The Company does not include any amounts subject to uncertainties in the transaction price until it is probable that the amount will not result in a significant reversal of revenue in the future. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price.

Because such agreements generally only have one type of performance obligation, a license, which is generally all transferred at the same time as agreement inception, allocation of the transaction price among multiple performance obligations is not required. Upfront amounts allocated to licenses are recognized as revenue when the licenses are transferred to the partners. Development milestones and other fees are recognized in revenue when their occurrence becomes probable.

Research and Development

Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, stock-based compensation expense, contract services, and other external development expenses. The Company records research and development activities conducted by third-party service providers, which include work related to preclinical studies, clinical trials, and contract manufacturing activities, to research and development expense as incurred. The Company is required to estimate the amount of services provided but not yet invoiced and include these expenses in accrued expenses on the balance sheet and within research and development expenses in the statements of operations and comprehensive loss. These expenses are a significant component of the Company's research and development expenses and require significant estimates and judgments. The Company accrues for these expenses based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. As actual expenses become known, the Company adjusts its accrued expenses.

Share-Based Compensation

The Company recognizes all stock-based payments to employees, including grants of employee stock options in the condensed consolidated statements of operations and comprehensive loss based on their fair values. All of the Company's share-based awards, to employees, non-employees, officers, and directors, are subject only to service-based vesting conditions. The Company estimates the fair value of its stock-based awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (i) the expected stock price volatility, (ii) the calculation of expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Options granted during the year have a maximum contractual term of ten years. Forfeitures are recognized and accounted for as they occur.

Due to the historical lack of a public market for the trading of the Company's securities and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company believes the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of the Company.

The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted to employees, officers, and directors using the simplified method, which represents the average of the contractual term of the stock option and its weighted-average vesting period, to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees, and utilizes the contractual term for options granted to non-employees. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected

term of the stock options. Compensation expense related to awards to employees is calculated on a straight-line basis by recognizing the grant date fair value over the associated service period of the award, which is generally the vesting term.

Income Taxes

Income taxes have been accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties related to uncertain tax positions, if any exist, in income tax expense.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Basic shares outstanding includes the weighted average effect of the Company's Pre-Funded Warrants issued in September 2022, the exercise of which requires little or no consideration for the delivery of shares of common stock. Basic and diluted weighted average shares of common stock outstanding for the three and nine months ended September 30, 2022, includes the weighted average effect of 2,426,493 Pre-Funded Warrants for the purchase of shares of common stock, for which the remaining unfunded exercise price is $0.0001 per share.

The following table computes the computation of the basic and diluted net loss attributable to common stockholders during the three and nine months ended September 30, 2021 (amounts in thousands except share and per share data). There were no cumulative dividends or other adjustments to net loss attributable to common stockholder during the three and nine months ended September 30, 2022.

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Numerator:		
Net loss	$ (87,088)	$ (94,100)
Cumulative dividends on convertible preferred stock	(154)	(647)
Net loss attributable to common stockholders	$ (87,242)	$ (94,747)
Denominator:		
Weighted-average common shares outstanding	9,510,379	4,890,556
Net loss per share attributable to common stockholders, basic and diluted	$ (9.17)	$ (19.37)

Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company’s potentially dilutive securities, which include convertible promissory notes, convertible preferred stock, outstanding stock options and warrants have been excluded from the computation of diluted net loss per share as they would be anti-dilutive.

Net loss per share is presented as the more dilutive of the treasury stock and as-converted method or the two-class method required for participating securities. The Series A convertible preferred stock is considered a participating security and does not have a contractual obligation to share in Private Aadi’s losses. As such, the two-class method was not required.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive (amounts in thousands):

	Nine Months Ended September 30,	
	2022	2021
Options to purchase common stock	**2,938**	1,298
Warrants to purchase common stock	**29**	37

Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU 2020-06, *"Debt – Debt with Conversion and Other Options"* (Subtopic 470-20) and "Derivatives and Hedging – Contracts in Entity's Own Equity" (Subtopic 815-40). This new guidance is intended to reduce the complexity of accounting for convertible instruments. The guidance also addresses how convertible instruments are accounted for in the diluted earnings per share calculation and requires enhanced disclosures about the terms of convertible instruments. Entities may adopt ASU 2020-06 using either a partial retrospective or fully retrospective method of transition. This ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years for smaller reporting companies. The Company is currently evaluating the impact the adoption of ASU 2020-06 will have on the Company's financial statements.

In 2016, the FASB issued ASU 2016-13 *"Financial Instruments - Credit Losses"* which (i) significantly changes the impairment model for most financial assets that are measured at amortized cost and certain other instruments from an incurred loss model to an expected loss model which will be based on an estimate of current expected credit loss; and (ii) provides for recording credit losses on available-for-sale debt securities through an allowance account. The standard also requires certain incremental disclosures. Subsequently, the FASB issued several ASUs to clarify, improve, or defer the adoption of ASU 2016-13. This ASU is effective for fiscal years beginning January 2023. The Company is currently evaluating the impact the adoption of ASU 2016-13 will have on the Company's financial statements.

3. Fair Value Measurement

The Company determines the fair value of its short-term investments based on one or more valuations from its investment accounting and reporting service provider. The investment service provider values the securities using a hierarchical security pricing model that relies primarily on valuations provided by an industry-recognized valuation service. Such valuations may be based on trade prices in active markets for identical assets (Level 1 inputs) or valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as quoted prices for similar assets, yield curves, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, and broker and dealer quotes, as well as other relevant economic measures.

The following table sets forth the recurring fair value of the Company's financial assets and liabilities, allocated into the Level 1, Level 2 and Level 3 hierarchy that were measured at fair value on a recurring basis (amounts in thousands):

	Fair Value Measurements as of September 30, 2022			
	Level 1	Level 2	Level 3	Total
Money market funds (1)	**$ 126,058**	**$ —**	**$ —**	**$ 126,058**
U.S. government treasury bills	**24,929**	**—**	**—**	**24,929**
Commercial paper (2)	**—**	**21,996**	**—**	**21,996**
Corporate bonds	**—**	**3,013**	**—**	**3,013**
Total financial assets	**$ 150,987**	**$ 25,009**	**$ —**	**$ 175,996**

	Fair Value Measurements as of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	$ 140,032	$ —	$ —	$ 140,032

(1) Included in cash and cash equivalents in the accompanying balance sheets.
(2) $1.7 million of commercial paper included in cash and cash equivalents in the accompanying balance sheets.

Intangible Asset Impairment

During the three and nine months ended September 30, 2021, the Company recognized an impairment of $74.2 million of the contract intangible asset acquired in connection with the Merger and reduced the contract intangible asset to its estimated fair value of $3.9 million at the Effective Time. This represented a Level 3 fair value measurement as factors used to develop the estimated fair value are unobservable inputs that are not supported by market activity.

During the nine months ended September 30, 2022, upon receipt of the Notice of Termination, the Company impaired the contract intangible asset by $3.7 million to its estimated fair value of zero (which represented a Level 3 fair value measurement) based on receipt of the formal notice of termination from Gossamer for the Gossamer License Agreement.

4. Short-Term Investments

The Company's short-term investments, which consist of highly liquid securities, are classified as available-for-sale and are stated at fair value. The following table summarizes the Company's short-term investments (in thousands):

	Maturity (In Years)	Amortized Cost	Unrealized Losses	Fair Value
Money market funds		**$ 126,058**	**$ —**	**$ 126,058**
U.S. government treasury bills	Less than 1	**25,000**	**(71)**	**24,929**
Commercial paper	Less than 1	**21,996**	**—**	**21,996**
Corporate bonds	Less than 1	**3,041**	**(28)**	**3,013**
Total		**$ 176,095**	**$ (99)**	**$ 175,996**

There were no gross unrealized gains and unrealized losses for cash equivalents and investments as of December 31, 2021.

5. Intangible Asset

The Company recorded a long-lived contract intangible asset as a result of the Merger, related to the Gossamer License Agreement, which was assumed in the Merger. In accordance with GAAP, for asset acquisitions, the excess purchase price over the fair value of the acquired assets and liabilities was ascribed to the acquired contract intangible asset. Due to the significant excess purchase price being allocated over the fair value of the acquired contract intangible asset, the Company determined that an indicator of impairment was present. The contract intangible asset was assessed for recoverability using an undiscounted cash flow model, which resulted in undiscounted cash flows below the carrying amount. At the Effective Time, the Company recognized an impairment of $74.2 million to bring the carrying amount of the contract intangible asset down to its estimated fair value of $3.9 million. The fair value estimate of the intangible asset relating to contingent cash flows expected from the out-licensing arrangement, of which 90% of any future net cash proceeds would be remitted to CVR Holders and paid through the CVRs. The useful life of the intangible asset was estimated to be approximately 14.3 years.

On April 25, 2022, the Company received a formal notice of termination from Gossamer for the Gossamer License Agreement, relating to Gossamer's GB004 product candidate, a legacy product candidate of the Company's predecessor, Aerpio, after Gossamer announced that its Phase 2 SHIFT-UC clinical trial studying GB004 in patients with mild-to-moderate active ulcerative colitis did not meet the primary or secondary endpoints at week 12 and the study was being terminated for lack of treatment benefit. The Gossamer License Agreement terminated effective July 24, 2022. Based on the termination of the Gossamer License Agreement, the Company fully impaired the intangible asset, $3.7 million, of which the Gossamer License Agreement is the underlying asset, during the nine months ended September 30, 2022.

Amortization expense was $0 and $87,000 for the three and nine months ended September 30, 2022, respectively, and $26,000 for the three and nine months ended September 30, 2021.

The following table shows the amortization expense and impairment of the finite lived intangible asset for the nine months ended September 30, 2022 (amounts in thousands):

	Nine Months Ended September 30, 2022
Intangible asset, December 31, 2021	**$ 3,811**
Less amortization	**(87)**
Impairment of contract intangible	**(3,724)**
Intangible asset, net, September 30, 2022	**$ —**

6. Accrued Liabilities

Details of accrued liabilities are presented as follows (amounts in thousands):

	September 30, 2022	December 31, 2021
Accrued bonus	**$ 3,752**	$ 1,465
Advanced customer payments	**2,307**	—
Accrued clinical	**2,225**	2,507
Accrued contract manufacturing	**1,543**	2,287
Accrued salaries and payroll	**1,286**	152
Accrued professional fees	**1,013**	1,948
Accrued other - sales related	**1,009**	—
Accrued other	**462**	344
Total accrued liabilities	**$ 13,597**	$ 8,703

7. Operating Lease

In April 2019, the Company entered into a twenty-eight month facility lease agreement for 2,760 square feet of office space in Pacific Palisades, California (the "Pacific Palisades Lease"). The Pacific Palisades Lease commenced on May 1, 2019, included four months of rent abatement and a rent escalation clause and was set to expire on August 31, 2021. In August 2021, the Company exercised its option to extend the term of the Pacific Palisades Lease for an additional three-year period and entered into an amendment to the lease agreement (the "Pacific Palisades Lease Amendment"). Pursuant to the Pacific Palisades Lease Amendment, the Company and the landlord agreed to extend the term for an additional period of three (3) years and six (6) months, until February 28, 2025, with an option to renew for an additional three (3) years in accordance with the terms of the Pacific Palisades Lease agreement. Included in the Pacific Palisades Lease Amendment were nine months of rent abatement and a rent escalation clause.

In April 2022, the Company entered into a lease agreement for 10,615 square feet of office space in Morristown, New Jersey (the "Morristown Lease"). The Morristown Lease has a term of seventy-three months, unless terminated sooner, and includes rent abatement for the first three months and the forty-seventh and forty-eighth calendar months after lease commencement. Included in the Morristown Lease agreement are fixed rent escalations of approximately 2% on each anniversary year of the lease term.

The following table summarizes information related to the Company's lease (amounts in thousands):

	September 30, 2022	December 31, 2021
Assets:		
Operating lease right-of-use assets	**$ 1,573**	$ 557
Liabilities:		
Operating lease liabilities, current	**$ 374**	$ 131
Operating lease liabilities, non-current	**1,347**	474
Total operating lease liabilities	**$ 1,721**	$ 605

Rent expense is being recorded on a straight-line basis. Rent expense for the three and nine months ended September 30, 2022 and 2021 is presented on the following table (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating leases rent expense	**$ 112**	$ 47	**$ 270**	$ 138

Cash paid for leases and included in operating cash flows for the three and nine months ended September 30, 2022 and 2021 is presented on the following table (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cash paid included in operating cash flows	**$ 80**	$ 37	**$ 170**	$ 127

The future minimum lease payments required under the operating lease as of September 30, 2022, are summarized below (amounts in thousands):

Future Minimum Lease Payments:	
2022	$ 121
2023	489
2024	502
2025	310
2026	230
Thereafter	388
Total minimum lease payments	$ 2,040
Less: amount representing interest	$ (319)
Present value of operating lease liabilities	$ 1,721
Less: operating lease liabilities, current	$ (374)
Operating lease liabilities, non-current	$ 1,347
Remaining lease term (in years)	4.77
Incremental borrowing rate	7.45 %

8. License Agreements

Celgene License Agreement

On April 9, 2014, the Company entered into a license agreement (as amended the “Celgene License Agreement”) with Celgene for exclusive rights for certain patents and a non-exclusive license for certain technology and know-how pertaining to FYARRO.

The Celgene License Agreement will remain in effect from the effective date of April 9, 2014 until expiration of all milestone and royalty payment obligations under the agreement, unless terminated by either of the parties upon giving an advance notice as specified in the Celgene License Agreement. Under the terms of the Celgene License Agreement, Celgene agreed to supply the Company with licensed products of FYARRO necessary for clinical or non-clinical development.

Under the terms of the Celgene License Agreement, Celgene is entitled to receive certain development milestone payments, royalties on net sales from licensed products under the agreement and any sublicense fees. During three and nine months ended September 30, 2022, $0.3 million and $0.7 million in royalties were accrued on net product sales recognized during the three and nine months ended September 30, 2022, respectively. However, no payments related to milestones were paid during the three and nine months ended September 30, 2022 or 2021.

On August 30, 2021, the Company and Celgene entered into Amendment No. 1 (the “Amendment”) to the Celgene License Agreement related to certain intellectual property rights of Celgene pertaining to the compound known as FYARRO. Under the terms of the Amendment, the Company paid Celgene $5.8 million representing 50% of the previously outstanding payment obligation under the terms of the Celgene License Agreement, following the Effective Time of the PIPE Financing. Pursuant to the terms of the Amendment, the remaining previously outstanding payment obligation of $5.8

million, is due on the third anniversary of the Effective Time, or August 26, 2024 plus any accrued and unpaid interest due thereon ("Balloon Payment"). The Balloon Payment shall accrue interest, beginning August 26, 2021 until paid in full, at a rate equal to 4.00% per annum based on the weighted average amount outstanding during the applicable calendar quarter, and interest is payable quarterly in arrears. In addition, the parties agreed to amend the royalty rates payable to Celgene based on net sales of products subject to the Celgene License Agreement.

On December 8, 2020, the Company entered into a license agreement ("EOC License Agreement") with EOC Pharma (Hong Kong) Limited ("EOC") under which the Company received $14.0 million in January 2021 in non-refundable upfront consideration as partial payment for the rights and licenses granted to EOC by the Company for the further development and commercialization of FYARRO in the People's Republic of China, Hong Kong Special Administration Region, Macao Special Administrative Region and Taiwan (the "Licensed Territory"). In accordance with the Celgene License Agreement, the Company is required to pay 20% of all sublicense fees to Celgene. As such, the Company recognized $2.8 million of license expense in the year ended December 31, 2020 and had a corresponding $2.8 million sublicense payable to Celgene on the balance sheet as of December 31, 2020, which was paid during the nine months ended September 30, 2021.

During the year ended December 31, 2021, the Company recognized license revenue and received $1.0 million from EOC for achieving the FDA approval milestone on November 22, 2021. In accordance with the Celgene License Agreement, the Company recognized $0.2 million of license expense in the year ended December 31, 2021 and had a corresponding $0.2 million sublicense payable to Celgene on the balance sheet as of December 31, 2021, which was paid in the nine months ended September 30, 2022.

EOC License Agreement

In December 2021, the Company entered into the EOC License Agreement with EOC for the further development of ABI-009, now called FYARRO, and commercialization of FYARRO in the Licensed Territory. Under the terms of the agreement, the Company granted to EOC an exclusive, royalty-bearing license to develop and commercialize the product in the Licensed Territory. The term of the EOC License Agreement was set to continue until the expiration of the royalty obligations under the agreement.

On June 27, 2022, the Company received written notice from EOC that EOC elected to terminate the EOC License Agreement, effective immediately, due to alleged material breaches by the Company under such agreement. The Company disagrees with, and continues to dispute, EOC's allegations of material breach and does not believe that EOC had a right to terminate the EOC License Agreement for material breach, and accordingly believes that the termination of the EOC License Agreement is a termination for convenience. EOC had the right to terminate the agreement for convenience upon 120 days advance written notice. The Company waived such notice period in connection with EOC's termination notice and, as a result, the EOC License Agreement was terminated effective June 27, 2022. Either party had the right to terminate the EOC License Agreement in the event that the other party breaches the agreement and fails to cure the breach, becomes insolvent or challenges certain of the intellectual property rights licensed under the agreement.

The Company assessed the EOC License Agreement and concluded that EOC is a customer and identified the license of ABI-009 provided to EOC as the sole performance obligation. The $14.0 million upfront payment received from EOC is non-refundable and non-creditable and is considered fixed consideration. The Company recognized revenue of $14.0 million in December 2020 when the EOC License Agreement was signed, and the $14.0 million upfront payment was received in January 2021.

The potential milestone payments and royalty payments under the EOC License Agreement were considered variable consideration and were constrained with respect to revenue recognition notification from EOC that the milestone and royalty payments had been achieved.

The Company was eligible to receive an additional $257.0 million in the aggregate upon achievement of certain development, regulatory, and sales milestones, as well as tiered royalties on net sales in the Licensed Territory. Under the terms of the EOC License Agreement, EOC was obligated to fund all research, development, regulatory, marketing and commercialization activities in the defined Licensed Territory. The Company earned $1.0 million in milestone revenue upon achievement of the FDA approval milestone on November 22, 2021. EOC paid the $1.0 million milestone payment in December 2021. In accordance with the Celgene License Agreement, 20% of the $1.0 million payment, or $0.2 million was accrued at December 31, 2021, and paid in January 2022.

9. Convertible Notes

Private Aadi received $8.1 million in October 2019 ("October 2019 Convertible Notes") and $1.0 million in January 2020 for the proceeds in connection with the issuance of convertible promissory notes ("January 2020 Convertible Notes," and together with October 2019 Convertible Notes "Convertible Notes"). The October 2019 Convertible Notes were issued to

existing equity holders of Private Aadi. The Convertible Notes originally had a maturity date of one year from the date of issuance and an escalating interest rate of 6% per annum for the first four months following the effective date of the loan agreement, 8% per annum for the fifth and sixth months, and 10% per annum for the remaining six months of the note term until maturity at twelve months.

In November 2020, Private Aadi entered into an amendment to the Convertible Notes, whereby the term was extended from one year to two years. The amendment was accounted for as a debt modification.

In May 2021, Private Aadi entered into an amendment to the Convertible Notes, whereby upon the closing of the Merger (see Note 1), the outstanding principal amount of the Convertible Notes and all accrued and unpaid interest as of immediately prior to the closing of the Merger would automatically convert into fully paid and nonassessable shares of Private Aadi common stock at a price per share equal to $4.80 and would be concurrently exchanged for shares of the Company's common stock based on the Exchange Ratio. In conjunction with the closing of the Merger on August 26, 2021, the outstanding Convertible Notes were converted into shares of Private Aadi common stock which were concurrently exchanged for 698,018 shares of the Company's common stock based on the Exchange Ratio. At the date of conversion, the Convertible Notes were marked to market and valued at $9.5 million, resulting in a gain on conversion of $0.4 million in the year ended December 31, 2021.

10. Payroll Protection Program Loan

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act also appropriated funds for the Small Business Administration ("SBA") Paycheck Protection Program ("PPP") loans that are forgivable in certain situations to promote continued employment, as well as Economic Injury Disaster Loans to provide liquidity to small businesses harmed by COVID-19.

In May 2020, Aadi was approved for a $0.2 million SBA PPP loan, as provided for in the CARES Act ("PPP Loan"). Under certain conditions, the PPP Loan and accrued interest are forgivable after a twenty-four-week covered period as long as the loan proceeds were used for eligible expenses, including payroll, benefits, rent and utilities, and the company maintains certain payroll levels. The amount of loan forgiveness is subject to reduction if the Company terminates employees or reduces salaries during the twenty-four-week covered period. The unforgiven portion of the loan is payable over two years at an interest rate of 1%, with a deferral of payments for the ten months following the end of the twenty-four-week covered period. On April 29, 2021, the Company received notification from the SBA that the Company's Forgiveness Application of the PPP Loan and accrued interest was approved in full, and the Company had no further obligations related to the PPP Loan. Accordingly, the Company recorded a gain on the forgiveness of the PPP Loan totaling $0.2 million.

11. Stockholders' Equity (Deficit)

Preferred Stock

As of September 30, 2022 and December 31, 2021, under the Company's certificate of incorporation, as amended and restated, the Company has 10,000,000 shares of preferred stock, par value $0.0001 per share, in authorized capital with no shares outstanding.

Series Seed Preferred Stock

On February 23, 2017, Private Aadi converted from a limited liability company to a corporation and at that time converted 734,218 membership units into shares of Series Seed Preferred Stock. All outstanding shares of Series Seed Preferred Stock were converted into Private Aadi's common stock and concurrently exchanged for the Company's common stock based on the Exchange Ratio in connection with the closing of the Merger.

Series A Preferred Stock

In February and March 2017, Private Aadi sold and issued in a private placement 5,847,940 shares of Series A Preferred Stock at $3.42 per share (the "Series A Financing"). Upon the closing of the Series A Financing, convertible notes issued in 2015 converted into 482,426 shares of Series A Preferred Stock at 85% of the $3.42 price per share (the "Series A Original Issue Price") paid by the Series A Financing investors. Convertible notes issued in 2017 converted into 881,286 shares of Series A Preferred Stock at the Series A Original Issue Price. All outstanding shares of Series A Preferred Stock were converted into shares of Private Aadi common stock and concurrently exchanged for the Company's common stock based on the Exchange Ratio in connection with the closing of the Merger.

Common Stock and Pre-Funded Warrants

As of September 30, 2022 and December 31, 2021, the Company had 300,000,000 shares of authorized common stock, par value of $0.0001 per share under the Company's certificate of incorporation, as amended and restated. As of September 30, 2022 and December 31, 2021, the shares of common stock outstanding were 24,395,117 and 20,894,695, respectively.

In conjunction with the closing of the Merger, the Company issued an aggregate of 2,558,218 shares of common stock to holders of Private Aadi common stock in exchange for all of the Private Aadi capital stock outstanding immediately prior to the closing of the Merger. Concurrently with the closing of the Merger, the PIPE Investors purchased an aggregate of 11,852,862 shares of the Company's common stock for an aggregate purchase price of $155.0 million pursuant to the Subscription Agreement entered into with the Company on May 16, 2021. The aggregate net proceeds, after deducting certain expenses incurred that were direct and incremental to the issuance of the PIPE shares, was $145.4 million.

In March 2022, the Company entered into the Sales Agreement with Cowen, with respect to an "at the market offering" program pursuant to which the Company may offer and sell, from time to time at its sole discretion, shares of common stock having aggregate gross proceeds of up to $75.0 million through Cowen as its sales agent. As of September 30, 2022, no shares of common stock had been sold pursuant to the Sales Agreement.

On September 22, 2022, the Company entered into the Purchase Agreement for the Private Placement Financing with the Private Placement Investors for the sale by the Company of 3,373,526 shares of the Company's common stock for a price of $12.50 per share and Pre-Funded Warrants to purchase an aggregate of 2,426,493 shares of the Company's common stock at a purchase price of $12.4999 per Pre-Funded Warrant. The Pre-Funded Warrants are exercisable at an exercise price of $0.0001 and will be exercisable until exercised in full. The Private Placement Financing closed on September 26, 2022. Aggregated net proceeds, after deducting certain expenses incurred of $0.3 million related to the issuance of the shares were $72.2 million.

On September 22, 2022, the Company and the Purchasers entered into the Private Placement Registration Rights Agreement providing for the registration for resale of the securities sold under the Purchase Agreement, including the shares issuable upon the exercise of the Pre-Funded Warrants, that are not then registered on an effective registration statement, pursuant to a registration statement filed with the SEC. The Pre-Funded Warrants meet the criteria to be classified within stockholders' equity.

Dividends

The holders of common stock are entitled to receive dividends, if and when declared by the board of directors of the Company (the "board of directors"). Since the Company's inception, no dividends have been declared or paid to the holders of common stock.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the Company, the holders of common stock are entitled to share ratably in the Company's assets.

Voting

The holders of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings.

12. Stock-Based Compensation

Stock Option Plan – 2014 Plan (as amended and restated in February 2017, the "Private Aadi Plan")

In connection with the Merger, the Company assumed the Private Aadi Plan, which was amended and restated in February 2017, and the issued and outstanding stock options under the Private Aadi Plan (the Private Aadi common stock underlying the awards was adjusted for shares of the Company's common stock pursuant to the Merger Agreement). The Private Aadi Plan allowed for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock unit awards and other stock awards. In connection with the closing of the Merger and the adoption of the 2021 Plan (as defined below), no further awards will be issued under the Private Aadi Plan.

The options that are granted from the Private Aadi Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The Private Aadi Plan stock options generally vest over a four-year term.

Stock Option Plan – 2011 Plan and 2017 Plan

In connection with the closing of the Merger, the Company assumed the Aerpio 2011 Equity Incentive Plan (the "2011 Plan") and the Aerpio 2017 Stock Option and Incentive Plan (the "2017 Plan," and together with the 2011 Plan, the "Prior

Plans"). No new awards will be granted under the Prior Plans effective as of the closing of the Merger and adoption of the 2021 Plan (as defined below).

Stock Option Plan – 2021 Plan

At the closing of the Merger, the Company adopted the Aadi Bioscience, Inc. 2021 Equity Incentive Plan (the "2021 Plan"), which permits the award of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance grants to employees, members of the board of directors, and outside consultants.

Subject to the adjustment provisions contained in the 2021 Plan and the evergreen provision described below, a total of 2,070,784 shares of common stock were initially reserved for issuance pursuant to the 2021 Plan. In addition, the shares reserved for issuance under the 2021 Plan include any shares of common stock (i) subject to awards of stock options or other awards granted under the Prior Plans that expire or otherwise terminate without having been exercised in full and shares of common stock granted under the Prior Plans that are forfeited or repurchased by the Company, and (ii) any shares of common stock subject to stock options or similar awards granted under the Private Aadi Plan that were assumed in the Merger (provided that the maximum number of shares that may be added to the 2021 Plan pursuant to this sentence is 764,154 shares).

The number of shares available for issuance under the 2021 Plan also will include an annual increase, or the evergreen feature, on the first day of each of the Company's fiscal years, beginning with the Company's fiscal year 2022, equal to the least of:

- 2,070,784 shares of common stock;
- a number of shares equal to 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year; or
- such number of shares as the board of directors or its designated committee may determine.

As a result of the evergreen increase, a total of 835,787 shares were added to the 2021 Plan on January 1, 2022.

Shares issuable under the 2021 Plan are authorized, but unissued, or reacquired shares of common stock. If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited to or repurchased by the combined company due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2021 Plan (unless the 2021 Plan has terminated).

As of September 30, 2022, zero, 314,502, 101,024 and 2,522,069 shares were outstanding under the 2011 Plan, Private Aadi Plan, 2017 Plan and 2021 Plan, respectively.

The following table summarizes the stock option activity during the nine months ended September 30, 2022:

	Stock Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, January 1, 2022	1,749,876	$ 20.71	8.48	$ 10,007
Granted	1,508,638	16.37		
Exercised	(119,396)	3.31		
Expired/cancelled	(201,523)	20.90		
Outstanding, September 30, 2022	**2,937,595**	**$ 19.85**	**8.78**	**$ 3,714**
Options exercisable, September 30, 2022	**510,324**	**$ 14.68**	**6.11**	**$ 2,715**

As of September 30, 2022, the aggregate intrinsic value of options outstanding was $3.7 million.

As of September 30, 2022, there was $28.6 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 2.86 years.

As of September 30, 2022, zero and 746,212 shares were reserved for issuance under the Private Aadi Plan and 2021 Plan, respectively.

Option Awards

During the three months ended September 30, 2022 and 2021, option awards to purchase an aggregate of 299,000 and 669,731 shares of common stock were granted, respectively.

During the nine months ended September 30, 2022 and 2021, option awards to purchase an aggregate of 1,508,638 and 727,620 shares of common stock were granted, respectively.

Compensation Expense Summary

The Company recognized the following compensation cost related to all employee and non-employee stock-based compensation activity for the periods presented (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Selling, general and administrative	**$ 1,840**	$ 524	**$ 4,492**	$ 543
Research and development	**917**	124	**2,281**	180
Total	**$ 2,757**	$ 648	**$ 6,773**	$ 723

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option pricing and models require the input of various assumptions, including the option's expected life, expected dividend yield, price volatility and risk-free interest rate of the underlying stock. Accordingly, the weighted-average fair value of the options granted during the nine months ended September 30, 2022 and 2021 was $9.93 and $19.24 per share, respectively.

The calculation was based on the following assumptions.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Expected term (years)	**6.08**	5.27 - 6.08	**5.50 - 6.08**	5.08 - 6.25
Risk-free interest rate	**2.65% - 3.15%**	0.84% - 1.15%	**1.46% - 3.38%**	0.84% - 1.15%
Expected volatility	**86.81% - 87.85%**	86.02% - 87.27%	**85.91% - 87.85%**	85.21% - 87.88%
Expected dividend yield	—	—	—	—

In connection with the retirement of an employee of the Company, the Company has modified its previously granted equity awards to continue vesting of 64,436 shares, which would have otherwise been forfeited in May 2022 as a result of such retirement and extended the exercise ability of the former employee's vested and outstanding options. The incremental stock-based compensation expense was not material for the three and nine months ended September 30, 2022.

Merger Warrants to Purchase Common Stock

The Company had warrants outstanding for the purchase of 29,166 and 36,666 shares of the Company's common stock at September 30, 2022 and December 31, 2021, respectively ("Merger Warrants"). These Merger Warrants were assumed in the Merger and were issued by Aerpio in October 2019, for the purchase of 40,000 shares (after taking into account the Reverse Stock Split) of the Company's common stock at an exercise price of $7.29 per share (after taking into account the Reverse Stock Split). These Merger Warrants were fully vested as of the date of the Merger and expire on October 24, 2024. During the three and nine months ended September 30, 2022, zero and 7,500 Merger Warrants were exercised, respectively. At the grant date, the fair value of these awards was determined using a Black-Scholes option pricing model.

The number of shares and the exercise price shall be adjusted for standard anti-dilution events such as stock splits, combinations, reorganizations, or issue shares as part of a stock dividend. The Merger Warrants meet the criteria to be classified within stockholders' equity.

13. Employee Stock Purchase Plan

On August 17, 2021, a special meeting of the Company's stockholders was held to approve the Merger and related matters, at which the Company's stockholders considered and approved the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP"). Upon approval of the 2021 ESPP by the stockholders, Aerpio's Amended and Restated 2017 Employee Stock Purchase Plan terminated. An aggregate of 310,617 shares of common stock (after taking into account the Reverse Stock Split) have been reserved and are available for issuance under the 2021 ESPP. The number of shares of common stock available for issuance under the 2021 ESPP will be increased on the first day of each fiscal year beginning with the 2022 fiscal year in an amount equal to the least of (i) 310,617 shares of common stock (after taking into account the Reverse Stock Split), (ii) one percent (1%) of the outstanding shares of all classes of common stock on the last day of the

immediately preceding fiscal year, or (iii) an amount to be determined by the board of directors or its designated committee no later than the last day of the immediately preceding fiscal year. Shares of common stock issuable under the 2021 ESPP will be authorized, but unissued, or reacquired shares of common stock. If the Company's capital structure changes because of a stock dividend, stock split or similar event, the number of shares that can be issued under the 2021 ESPP will be appropriately adjusted. The Company opened enrollment into the ESPP in May 2022.

As a result of the evergreen increase described above, a total of 208,946 shares were added to the 2021 ESPP on January 1, 2022. No shares under the 2021 ESPP were issued through September 30, 2022.

14. Income Taxes

The Company recorded income tax expense of zero and $9,000 for the three and nine months ended September 30, 2022 and zero and $2,000 for the three and nine months ended September 30, 2021. The Company continues to maintain a full valuation allowance.

15. Commitments and Contingencies

Legal Proceedings

From time to time, the Company could be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Regardless of the outcome, legal proceedings can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors.

On June 27, 2022, EOC filed a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against the Company. In the Request for Arbitration, EOC claims that the Company breached certain provisions of the EOC License Agreement, including failing to provide certain manufacturing and clinical development information to EOC. As a result, EOC is seeking monetary damages. The arbitration process is ongoing. The Company intends to defend itself vigorously in this matter and pursue all relief to which the Company is entitled. The Company is unable to estimate the possible loss or range of loss, therefore no amounts have been accrued as of September 30, 2022.

Purchase Commitments

The Company has ongoing contracts with vendors for clinical trials and contract manufacturing. These contracts are generally cancellable, with notice, at the Company's option. The Company recorded accrued expenses of $3.8 million and $4.8 million in its condensed consolidated balance sheet for expenditures incurred by clinical and contract manufacturing vendors as of September 30, 2022 and December 31, 2021, respectively.

At September 30, 2022, the Company had one significant contract with Fresenius Kabi that contains specific activities such as non-cancellable commitments, minimum purchase commitments, or binding annual forecasts.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") 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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- our ability to maintain regulatory approval for FYARRO® in advanced malignant perivascular epithelioid cell tumors ("PEComa"), or to obtain and maintain regulatory approval for FYARRO in additional indications, or any other product candidates we may develop in the future, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our plans and potential for success relating to commercializing FYARRO, or any other product candidate that we may develop, if approved;
- our plans related to the further development and manufacturing of FYARRO;
- the timing, scope or likelihood of regulatory filings and approvals for FYARRO for advanced malignant PEComa in foreign jurisdictions and any additional indications we may pursue and any other product candidates we may develop in the future;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing and reimbursement of FYARRO and any other product candidates we may develop in the future, if approved;
- the rate and degree of market acceptance of FYARRO and any other product candidates we may develop in the future, if approved;
- the timing, progress and results of preclinical studies and clinical trials for our programs and product candidates, including the anticipated impact of the COVID-19 pandemic, the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO and any other product candidates that we may develop in the future;
- our ability to develop and advance product candidates into, and successfully complete, clinical studies;
- the implementation of our business model and our strategic plans for our business;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our ability to contract with and rely on third parties to assist in conducting our clinical trials and manufacturing FYARRO and any other product candidates we may develop in the future;
- the size and growth potential of the markets for FYARRO and any other product candidates we may develop in the future, if approved, and our ability to serve those markets, either alone or in partnership with others;
- our ability to obtain funding for our operations, including funding necessary to commercialize FYARRO and to complete further development, approval and, if approved, commercialization of FYARRO in additional indications and any other product candidates we may develop in the future;
- the period over which we anticipate our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our ability to compete with other companies currently marketing or engaged in the development of treatments for the indications that we are pursuing for FYARRO and any other product candidates we may develop in the future;

- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our financial performance;
- statements regarding the legal proceedings related to the termination of the EOC License Agreement;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

Forward-looking statements are not historical facts, but rather are based on current expectations, estimates, assumptions, and projections about the business and future financial results of the pharmaceutical industry, and other legal, regulatory and economic developments. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “intend,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “predict,” “potential,” “continue,” “likely,” and similar expressions (including their use in the negative) intended to identify forward-looking statements although not all forward-looking statements contain these identifying words. Actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including, but not limited to, those described in Part II, Item 1A (Risk Factors) of this Quarterly Report.

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with or furnished to the U.S. Securities and Exchange Commission (the “SEC”) completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

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

References in the following discussion to “we,” “our,” “us,” or “Aadi” refer to Aadi Bioscience, Inc. and its subsidiaries.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the related notes to those statements thereto appearing elsewhere in this Quarterly Report and our audited consolidated financial statements and related notes thereto included in our Annual Report on Form 10-K filed with the SEC on March 17, 2022. Some of the information contained in this discussion and analysis including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risk, uncertainties and assumptions. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report. You should read this Quarterly Report completely, including Part II, Item 1A (Risk Factors) of this Quarterly Report and the "Cautionary Statement Regarding Forward-Looking Statements" sections of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by our forward-looking statements contained in the following discussion and analysis. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We are a biopharmaceutical company focused on developing and commercializing precision therapies for genetically defined cancers with alterations in mTOR pathway genes. Our lead drug product, FYARRO®, is a form of sirolimus bound to albumin. Sirolimus is a potent inhibitor of the mTOR biological pathway, the activation of which pathway can promote tumor growth, and inhibits downstream signaling from mTOR.

In November 2021, the U.S. Food and Drug Administration (the "FDA") approved FYARRO sirolimus protein-bound particles for injectable suspension (albumin-bound) for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor ("PEComa"). On February 22, 2022, we launched FYARRO in the United States for treatment of advanced malignant PEComa and recognized net product sales of $4.2 million and $10.0 million for the three and nine months ended September 30, 2022, respectively.

In addition to advanced malignant PEComa, based on data from our completed Phase 2 registrational study, Advanced Malignant PEComa Trial ("AMPECT"), and our expanded access program, we have initiated a registration-directed tumor-agnostic Phase 2 study ("PRECISION 1") of FYARRO in patients with Tuberous Sclerosis Complex 1 and 2 ("*TSC1* & *TSC2*") alterations. We have completed a Type B meeting with the FDA in which we discussed the initial trial design and the PRECISION 1 trial was opened for enrollment in the United States during the first quarter of 2022. Our first patient was dosed in March 2022.

Recent Developments

- *Leadership Transition*. On November 8, 2022, we announced the appointment of Neil Desai, our founder, director, President and Chief Executive Officer, to Executive Chairman, and Brendan Delaney, our Chief Operating Officer, to President and Chief Executive Officer, effective as of January 1, 2023. Both Dr. Desai and Mr. Delaney will serve on our board of directors after the transition.
- *Private Placement Financing*. On September 22, 2022, we entered into a securities purchase agreement ("Purchase Agreement") for a private placement (the "Private Placement Financing") with certain investors ("Private Placement Investors"). Upon closing the Private Placement Financing on September 26, 2022, we sold (i) 3,373,526 shares of our common stock, at a purchase price of $12.50 per share, and (ii) 2,426,493 pre-funded warrants (the "Pre-Funded Warrants") to purchase shares of our common stock, at a purchase price of $12.4999 per Pre-Funded Warrant. The Pre-Funded Warrants will have an exercise price of $0.0001 per share of common stock, be immediately exercisable and remain exercisable until exercised in full. In connection with the Private Placement Financing, we entered into a Registration Rights Agreement, dated September 22, 2022 ("Private Placement Registration Rights Agreement"), with the Private Placement Investors. Pursuant to the Private Placement Registration Rights Agreement, on October 26, 2022, we filed a registration statement with the Securities and Exchange Commission (the "SEC") for the registration for resale of the securities sold under the Purchase Agreement, including the shares issuable upon the exercise of the Pre-Funded Warrants.

  At the closing of the Private Placement Financing, the total purchase price paid by the Private Placement Investors was approximately $72.2 million, after deducting $0.3 million of our offering expenses. We intend to use the net proceeds from the Private Placement Financing to fund working capital and other general corporate purposes.
- *Mirati Collaboration*. In October 2022, we entered into a collaboration and supply agreement with Mirati Therapeutics, Inc. ("Mirati") to evaluate the combination of Mirati's adagrasib, a $KRAS^{G12C}$ selective inhibitor,

and FYARRO in KRAS ^{G12C} mutant non-small cell lung cancer (NSCLC) and other solid tumors. Under the terms of the agreement, Mirati will be responsible for sponsoring and operating the Phase 1/2 study and we will supply study drug and jointly share the cost of the study.

The primary objective of this multi-center, single-arm, open-label Phase 1/2 trial is to determine the optimal dose and recommended Phase 2 dose for the combination of adagrasib and FYARRO in patients with KRAS^{G12C}-mutant solid tumors. In addition, the study will investigate the safety, tolerability and efficacy of adagrasib and FYARRO in combination in patients both with and without prior exposure to a KRAS^{G12C} inhibitor. The trial will build on preclinical data showing enhanced anti-tumor efficacy with the combination of adagrasib and FYARRO relative to either agent alone.

Celgene License Agreement

In April 2014, Private Aadi entered into a license agreement (the "Celgene License Agreement") with Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, now Bristol-Myers Squibb Company ("Celgene"), for exclusive rights for certain patents and a non-exclusive license for certain technology and know-how pertaining to ABI-009 (which we refer to as FYARRO). Under the Celgene License Agreement, as amended, Celgene is entitled to receive certain development milestone payments, royalties on net sales from licensed products under the agreement and any sublicense fees. During the three and nine months ended September 30, 2022, we recorded royalties of $0.3 million and $0.7 million, under the terms of this agreement. No payments related to milestones under this agreement were paid during the three and nine months ended September 30, 2022. See Note 8 to the condensed consolidated financial statements for more information about the Celgene License Agreement.

Under the terms of an August 2021 amendment to the Celgene License Agreement, we paid Celgene $5.8 million, representing 50% of the previously outstanding payment obligation under the terms of the Celgene License Agreement, following the effective time of the PIPE financing that occurred in connection with the closing of the reverse acquisition of Aerpio Pharmaceuticals, Inc. Pursuant to the terms of the amendment, the remaining portion of the previously outstanding payment obligation ($5.8 million), which is recorded on our balance sheet as due to licensor, is due on the third anniversary of the effective time of such PIPE financing plus any accrued and unpaid interest due thereon.

EOC License Agreement

In December 2020, we entered into the EOC License Agreement with EOC under which we received $14.0 million in January 2021 in non-refundable upfront consideration as partial payment for the rights and licenses granted to EOC by us for the further development and commercialization of FYARRO in the People's Republic of China, Hong Kong Special Administration Region, Macao Special Administrative Region and Taiwan (the "Licensed Territory"). In accordance with the Celgene License Agreement, we are required to pay 20% of all sublicense fees to Celgene. As such, we recognized $2.8 million of license expense in the fourth quarter of 2020 and had a corresponding $2.8 million sublicense payable to Celgene on the balance sheet as of December 31, 2020, which was paid in 2021.

During the fourth quarter of 2021, we recognized license revenue and received $1.0 million from EOC for achieving the FDA approval milestone in November 2021. In accordance with the Celgene License Agreement, we recognized $0.2 million of license expense in the fourth quarter of 2021 and had a corresponding $0.2 million sublicense payable to Celgene on the balance sheet as of December 31, 2021, which was paid in 2022.

On June 27, 2022, we received written notice from EOC that EOC has elected to terminate the EOC License Agreement, effective immediately. See Note 8 to the condensed consolidated financial statements for more information about the EOC License Agreement and its termination.

Key Trends and Factors Affecting Comparability Between Periods

- Commercial sale of FYARRO was launched on February 22, 2022, for the treatment of patients with advanced malignant PEComa. We recorded net product sales of $4.2 million and $10.0 million during the three and nine months ended September 30, 2022, respectively.
- We have built a cross-functional commercial team consisting of marketing, market access and commercial operations and will continue to strategically build our sales and our commercial infrastructure with capabilities designed to scale when necessary to support future commercial launches. Expenses related to our commercial launch including personnel expenses, sales support, and marketing are included in selling, general and administrative expenses for the three and nine months ended September 30, 2022. We expect these expenses will continue to increase, as compared to prior periods, with the launch of FYARRO and preparation for potential future launches.

- We continue to build out our research and development team and we expect our research and development costs will increase in 2022, relative to 2021, as a result of significant expenses related to the PRECISION 1 trial which was open to enrollment during the nine months ended September 30, 2022, with the first patient dosed in March 2022.
- As a public company our expenses have increased from prior year as a privately held company, including (i) costs to comply with the rules and regulations of the SEC and those of the Nasdaq Capital Market ("Nasdaq"), (ii) legal, accounting and other professional services, (iii) insurance, (iv) investor relations activities, and (v) other administrative and professional services.
- The COVID-19 pandemic has resulted, and is likely to continue to result in, significant national and global economic disruption and may adversely affect our operations. Our clinical trials have been, and may continue to be, affected by the closure of offices, lack of resources or closure of borders, among other measures being put in place around the world. The inability to travel and conduct face-to-face meetings, as well as constraints surrounding hospital infrastructure and staff, can also make it more difficult to enroll and maintain patients in ongoing or planned clinical trials. We are actively monitoring the impact of COVID-19 and the possible effects on our financial condition, liquidity, operations, suppliers, industry and workforce. However, the full extent, consequences and duration of the COVID-19 pandemic and the resulting impact on us cannot currently be predicted. We will continue to evaluate the impact that these events could have on our operations, financial position, results of operations and cash flows in fiscal year 2022.

Liquidity and Capital Resources

As of September 30, 2022, we had $183.0 million of cash, cash equivalents and short-term investments. Based on our current plans, we believe our existing cash, cash equivalents and short-term investments will enable us to conduct our planned operations into 2025. We have incurred net losses in each year since inception and as of September 30, 2022 we had an accumulated deficit of $189.3 million. These losses have resulted principally from costs incurred in connection with research and development activities, selling, general and administrative costs associated with our operations, and costs associated with the Merger. We expect to continue to incur significant expenses and operating losses for the foreseeable future due to the cost of research and development, including conducting preclinical and clinical trials and identifying and designing product candidates, the regulatory approval process for FYARRO outside the United States and in additional indications and any other product candidates we may develop in the future and the commercial launch of FYARRO.

Basis of Presentation

The following discussion highlights our results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described and provides information that management believes is relevant for an assessment and understanding of the condensed consolidated balance sheets and statements of operations and comprehensive loss presented herein. The following discussion and analysis are based on our condensed consolidated financial statements contained in this Quarterly Report, which we have prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). You should read the discussion and analysis together with such condensed consolidated financial statements and the related notes thereto.

Components of Statements of Operations and Comprehensive Loss

Revenue

Product Sales, Net

FYARRO was approved by the FDA in November 2021. On February 22, 2022, we launched sales of FYARRO to specialty distributors ("SD"s) and a specialty pharmacy ("SP"). We recognize product sales when the SDs and SP obtain control of the product, which occurs upon delivery. Product sales are recorded at the net sales price, which includes provisions for the following allowances which are reflected either as a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

- *Distribution Fees*: Distribution fees include distribution service fees paid to the SDs and SP based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"). Distribution fees are recorded as an offset to product sales based on contractual terms at the time the sale is recognized.
- *Rebates*: Allowance for rebates include mandated discounts under the Medicaid Drug Rebate Program and TRICARE program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. Our estimates for expected utilization of rebates are based on utilization data received from the SDs and SP since product

launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

- *Chargebacks:* Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs and SP at a discounted price. The SDs and SP charge back to us the difference between the price initially paid by the SDs and SP and the discounted price paid to the SDs and SP by these entities. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect product sales in the period of adjustment.
- *Co-Payment Assistance:* We offer co-payment assistance to commercially insured patients meeting certain eligibility requirement. Co-payment assistance is accrued at the time of product sale to the SDs and SP based on estimated patient participation and average co-pay benefit to be paid per a claim. Our estimated amounts are compared to actual program participation and co-pay amounts paid using data provided by third-party administrators. If actual amounts differ from the original estimates the assumptions being applied are updated and adjustment for prior period accruals will be adjusted in the current period.
- *Product Returns:* Consistent with industry practice, we offer the SDs and SP limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. We do not allow product returns for product that has been dispensed to a patient. As we receive inventory reports from the SDs and SP and have the ability to control the amount of product that is sold to the SDs and SP, we estimate future potential product returns based on the this on-hand channel inventory data and sell-through data obtained from the SDs and SP. In arriving at its estimate, we also consider historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

Grant Revenue

Grant revenue is derived from federal grants, primarily with the FDA. We have determined that the government agencies providing grants to us are not customers. Grant revenue is recognized when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received. We recognize grant revenue as reimbursable grant costs are incurred. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

With respect to grant revenue derived from reimbursement of direct out-of-pocket expenses for research costs associated with federal contracts, where we act as principal with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we record revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, business development, sales and marketing, and other corporate functions. Other general and administrative expenses include professional fees for legal, auditing, tax and business consulting services, insurance costs, intellectual property and patent costs, facility costs and travel costs. We expect that selling, general and administrative expenses will increase in the future as we expand our operating activities. Additionally, we have incurred, and expect to continue to incur, significant additional expenses associated with being a public company that we did not incur as a privately held company, including (i) costs to comply with the rules and regulations of the SEC and those of Nasdaq, (ii) legal, accounting and other professional services, (iii) insurance, (iv) investor relations activities and (v) other administrative and professional services.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of: (i) employee related costs, including salaries, benefits and stock-based compensation expense for employees engaged in scientific research and development functions; (ii) third-party contract costs relating to research, formulation, manufacturing, nonclinical studies and clinical trial activities; (iii) external costs of outside consultants who assist with technology development, regulatory affairs, clinical development and quality assurance; (iv) payments made under our third-party licensing agreements; and (v) allocated facility-related costs.

Costs for certain activities, such as manufacturing, nonclinical studies and clinical trials are generally recognized based on the evaluation of the progress of completion of specific tasks using information and data provided by our vendors and collaborators. Research and development activities are central to our business. We expect to increase our investment in research and development in order to advance FYARRO in additional indications through clinical trials. As a result, we expect that our research and development expenses will increase substantially in the foreseeable future as we continue to invest in research and development activities, pursue clinical development of FYARRO in additional indications and any other product candidates we may develop in the future and expand our product candidate pipeline.

The process of commercialization and conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. 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. Accordingly, to the extent that our product candidates continue to advance into clinical trials, including larger and later-stage clinical trials, our expenses will increase substantially and may become more variable.

Impairment of Acquired Contract Intangible Asset

Impairment of acquired contract intangible asset relates to a write down of the acquired contract intangible asset to fair value. During the nine months ended September 30, 2022, we recognized an impairment of $3.7 million to fully impair the contract intangible asset based on Gossamer's termination of the Gossamer License Agreement as a result of Gossamer not meeting its primary or secondary endpoint in the UC-SHIFT clinical trial.

Cost of Goods Sold

Cost of goods sold consist primarily of royalties paid to Celgene, costs incurred on sales of FYARRO and costs to manufacture and prepare the product for sales subsequent to the FDA approval in November 2021. Costs incurred prior to the FDA approval were expensed when incurred.

Other Income, Net

Other income, net consists of the change in fair value of convertible promissory notes and interest expense related to such notes. These expenses are partially offset by interest income earned on cash and cash equivalents and gain on extinguishment of debt.

Income Tax Expense

During the three and nine months ended September 30, 2022, we recognized zero and $9,000 of income tax expense on the statement of operations, respectively. During the three and nine months ended September 30, 2021, we recognized zero and $2,000 of income tax expense on the statement of operations, respectively. Since our formation in 2011, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned tax credits, due to our uncertainty of realizing a benefit from those items.

Results of Operations:

The following table presents the results of operations for the periods indicated (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Product sales, net	**$ 4,245**	$ —	**$ 9,989**	$ —
Grant revenue	**—**	—	**—**	120
Total revenue	**4,245**	—	**9,989**	120
Operating expenses				
Selling, general and administrative	**9,915**	7,401	**29,069**	8,793
Research and development	**8,773**	5,754	**23,292**	12,443
Cost of goods sold	**593**	—	**1,113**	—
Impairment of acquired contract intangible asset	**—**	74,156	**3,724**	74,156
Total operating expenses	**19,281**	87,311	**57,198**	95,392
Loss from operations	**(15,036)**	(87,311)	**(47,209)**	(95,272)
Other income, net	**562**	223	**618**	1,174
Loss before income tax expense	**(14,474)**	(87,088)	**(46,591)**	(94,098)
Income tax expense	**—**	—	**(9)**	(2)
Net loss	**$ (14,474)**	$ (87,088)	**$ (46,600)**	$ (94,100)

Comparison of the Three and Nine Months Ended September 30, 2022 and 2021

Product Sales, Net

Our product sales, net consist of sales of FYARRO since its launch in the United States on February 22, 2022. Product sales, net for the three and nine months ended September 30, 2022 were $4.2 million and $10.0 million, respectively. There were no product sales for the three and nine months ended September 30, 2021.

Grant Revenue

Grant revenue amounts can vary from period to period depending on the funding and work performed. Grant revenue decreased by $0.1 million for the nine months ended September 30, 2022, compared to the same period in 2021, primarily due to a decrease in the eligible expenses for grant reimbursement incurred during the 2022 period compared to 2021. The period for eligible grant reimbursement with the FDA ended during the nine months ended September 30, 2021. There were no new grants during the nine months ended September 30, 2022.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2022, were $9.9 million, an increase of $2.5 million, compared to $7.4 million for the three months ended September 30, 2021. The increase was driven by $2.4 million of personnel expenses related to increased headcount, incentive bonuses and share-based compensation and $0.7 million of legal, insurance and other related expenses, offset by a decrease of $0.6 million of consulting expenses.

Selling, general and administrative expenses for the nine months ended September 30, 2022, were $29.1 million, an increase of $20.3 million, compared to $8.8 million for the nine months ended September 30, 2021. The increase was driven by $9.3 million of personnel expenses related to increased headcount, incentive bonuses and share-based compensation, $5.2 million of legal, insurance and other related expenses, $3.2 million of commercial and marketing expenses, and $2.6 million of consulting expenses.

Research and Development Expenses

The following table presents our research and development expenses for the periods indicated (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Personnel expenses	**$ 4,800**	$ 885	**$ 12,925**	$ 2,084
Consultants	**829**	827	**3,362**	1,341
External clinical development	**2,529**	1,545	**5,425**	3,927
Clinical drug product manufacturing	**285**	2,455	**796**	4,967
Other expenses	**330**	42	**784**	124
Total research and development expenses	**$ 8,773**	$ 5,754	**$ 23,292**	$ 12,443

Research and development expenses for the three months ended September 30, 2022, were $8.8 million, an increase of $3.0 million, compared to $5.8 million for the three months ended September 30, 2021. The increase was primarily driven by a $4.1 million increase in headcount, consultants, and other expenses, and $1.0 million of clinical development expenses related to the PRECISION 1 trial, offset by a decrease of clinical drug product manufacturing of $2.1 million.

Research and development expenses for the nine months ended September 30, 2022, were $23.3 million, an increase of $10.9 million, compared to $12.4 million for the nine months ended September 30, 2021. The increase was primarily driven by $13.5 million in personnel, consulting and other expenses and $1.5 million of clinical development expenses related to the PRECISION 1 trial, offset by a decrease of clinical drug product manufacturing of $4.1 million.

Cost of Goods Sold

Cost of goods sold was $0.6 million and $1.1 million reflecting primarily royalties incurred on product sold during the three and nine months ended September 30, 2022, respectively. There were no cost of goods sold during the three and nine months ended September 30, 2021.

Impairment of Acquired Contract Intangible Asset

During the three and nine months ended September 30, 2022, we recorded zero and a $3.7 million impairment charge to reduce the carrying value of the intangible asset to its fair value of zero, based on a formal notice of termination we received on April 25, 2022 from Gossamer for the Gossamer License Agreement. The Gossamer License Agreement terminated effective July 24, 2022.

During the three and nine months ended September 30, 2021, we recorded a $74.2 million impairment charge to reduce the carrying value of the intangible asset to its fair value to $3.9 million at the Effective Time, as a result of the excess fair value ascribed to the acquired contract intangible asset related to the Merger.

Other Income, Net

Other income, net for the three months ended September 30, 2022 was $0.6 million, compared to $0.2 million for the three months ended September 30, 2021. The change was primarily driven by an increase in interest income during the three months ended September 30, 2022 compared to non-cash expense related to the change in fair value of the convertible promissory notes during the three months ended September 30, 2021.

Other income, net for the nine months ended September 30, 2022 was $0.6 million, compared to $1.2 million, for the nine months ended September 30, 2021. The change was primarily driven by the non-cash expense related to the change in fair value of the convertible promissory notes during the three months ended September 30, 2021 compared to interest expense during the three months ended September 30, 2022.

Liquidity and Capital Resources

Overview

As of September 30, 2022 we had $183.0 million of cash, cash equivalents and short-term investments. Based on our current plans, we believe our existing cash, cash equivalents and short-term investments will enable us to conduct our planned operations into 2025.

We have incurred net losses in each year since inception and as of September 30, 2022, we had an accumulated deficit of $189.3 million. Our net losses were $14.5 million and $87.1 million for the three months ended September 30, 2022 and 2021, respectively, and $46.6 million and $94.1 million for the nine months ended September 30, 2022 and 2021,

respectively. These losses have resulted principally from costs incurred in connection with research and development activities, selling, general and administrative costs associated with our operations, and costs associated with the Merger. We expect to continue to incur significant expenses and operating losses for the foreseeable future due to the cost of research and development, including conducting preclinical studies and clinical trials, identifying and designing product candidates, the regulatory approval process for FYARRO outside the United States and in additional indications and any other product candidates we may develop in the future, and the commercial launch of FYARRO. We expect our expenses, and the potential for losses, to increase substantially as we conduct clinical trials of FYARRO in additional indications and seek to expand our pipeline.

From inception through September 30, 2022, we received funding of $25.4 million from our initial seed financing and the sale of Series A convertible preferred stock, $9.1 million from the issuance of convertible promissory notes, $145.4 million, net from the PIPE Financing in connection with the Merger, $29.7 million of cash assumed in the Merger, and $72.2 million, net cash proceeds from the Private Placement Financing.

On March 17, 2022, we entered into a Sales Agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”), with respect to an “at the market offering” pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock having aggregate gross proceeds of up to $75.0 million through Cowen as our sales agent. Under the Sales Agreement, we will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitations on the number or dollar value of shares that may be sold in any one trading day and any minimum price below which sales may not be made. We will pay Cowen 3.0% of the aggregate gross proceeds from each sale of shares of common stock under the Sales Agreement. As of September 30, 2022, no shares of common stock had been sold under the Sales Agreement.

The shares of our common stock to be offered and sold under the Sales Agreement will be issued and sold pursuant to our shelf registration statement on the Form S-3 (File No. 333-255129), which was filed with the SEC on April 8, 2021, and which became effective on April 15, 2021. We filed a prospectus supplement with the SEC on March 21, 2022 in connection with the offer and sale of the shares pursuant to the Sales Agreement.

The shelf registration statement allows us to sell from time to time up to $150.0 million of common stock, preferred stock, debt securities, warrants, or units comprised of any combination of these securities, for our own account in one or more offerings. The shelf registration statement is intended to provide us flexibility to conduct registered sales of our securities, subject to market conditions and our future capital needs. The terms of any offering under the shelf registration statement will be established at the time of such offering and will be described in a prospectus supplement filed with the SEC prior to the completion of any such offering.

On September 22, 2022, the Company entered into the Purchase Agreement for the Private Placement Financing with the Private Placement Investors for the sale by the Company of 3,373,526 shares of the Company’s common stock for a price of $12.50 per share and Pre-Funded Warrants to purchase an aggregate of 2,426,493 shares of the Company's common stock, at a purchase price of $12.4999 per Pre-Funded Warrant. The Pre-Funded Warrants are exercisable at an exercise price of $0.0001 and will be exercisable until exercised in full. The Private Placement Financing closed on September 26, 2022. Aggregated net proceeds, after deducting certain expenses incurred of $0.3 million related to the issuance of the shares were $72.2 million.

The following table presents our cash flows for the periods indicated (amounts in thousands):

	Nine Months Ended September 30,	
	2022	**2021**
Net cash used in operating activities	**$ (38,330)**	$ (9,995)
Net cash (used in) provided by investing activities	**(48,507)**	25,199
Net cash provided by financing activities	**72,727**	141,716
Net (decrease) increase in cash, cash equivalents and restricted cash	**$ (14,110)**	$ 156,920

Operating Activities

Our cash used in operating activities primarily results from our net loss adjusted for non-cash expenses, changes in working capital components, amounts due to contract research organizations to conduct our clinical programs and employee-related expenditures for research and development and general and administrative activities. Our cash flows from operating activities will continue to be affected by spending to advance and support FYARRO in additional indications in the clinic and other operating and general administrative activities, including operating as a public company.

For the nine months ended September 30, 2022, cash used in operating activities was $38.3 million and resulted from (i) our net loss of $46.6 million, and (ii) $2.5 million net decrease in our working capital accounts, primarily driven by an increase in prepaid expenses, and accounts receivable and inventory related to the commercial launch of FYARRO in February 2022, and a decrease in accounts payable and accrued expenses; offset by non-cash adjustments totaling $10.7 million, which was primarily related to the impairment of the contract intangible asset, share based compensation, depreciation and amortization.

For the nine months ended September 30, 2021, cash provided by operating activities was $10.0 million and resulted from (i) our net loss of $94.1 million, offset by $73.8 million in non-cash expenses related primarily to the impairment of the acquired contract intangible asset of $74.2 million, and (ii) a $10.3 million net increase in our working capital accounts, primarily driven by the receipt of the $14.0 million upfront payment on accounts receivable pursuant to the EOC License Agreement.

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2022 related to purchases of fixed assets of $0.4 million and short-term investments of $48.1 million.

Cash provided by investing activities for the nine months ended September 30, 2021 related to cash acquired in connection with the Merger of $29.7 million offset by $4.5 million of transaction related expenses.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2022 related to $72.5 million gross cash proceeds from our Private Placement Financing, $0.4 million from exercise of stock options and $0.1 million from exercise of warrants offset by $0.2 million of deferred financing costs related to the Sales Agreement.

Cash provided by financing activities for the nine months ended September 30, 2021 related to $155.0 million gross cash proceeds from our PIPE Financing and $0.7 million from exercise of stock options, partially offset by $9.6 million of issuance costs related to the PIPE Financing, and $4.4 million of dividends paid to preferred stockholders.

Contractual Obligations and Commitments

In April 2022, we entered into a lease for 10,615 square feet of office space in Morristown, New Jersey. The term of the lease is seventy-three months unless terminated sooner.

Rent expense is being recorded on a straight-line basis. Rent expense related to the Pacific Palisades and Morristown leases was $0.3 million and $0.1 million for the nine months ended September 30, 2022 and 2021, respectively.

In January 2022, we entered into a Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product (the “Fresenius Agreement”) with Fresenius Kabi, LLC (“Fresenius Kabi”), pursuant to which Fresenius Kabi will manufacture FYARRO for intravenous use for us. The Fresenius Agreement contains specific activities such as non-cancellable commitments, minimum purchase commitments, or binding annual forecasts, and shall be effective through December 31, 2022 or such later date as may be agreed between the parties in writing.

In August 2021, we entered into an amendment to extend the lease of our 2,760 square feet of office space in Pacific Palisades, California. We exercised an option, under our prior lease agreement, to extend the term of the lease for an additional three-year period. Included in the renewal were nine months of rent abatement and a rent escalation clause.

We also have contracts with various organizations to conduct research and development activities, including clinical trial organizations to manage clinical trial activities and manufacturing companies to manufacture the drug product used in the clinical trials. The scope of the services under these research and development contracts can be modified and the contracts cancelled by us upon written notice. In the event of a cancellation, we would be liable for the cost and expenses incurred to date as well as any close out costs of the service arrangement.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). These accounting principles require us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. We believe that the estimates, judgments and assumptions are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. Historically, revisions to our estimates have not resulted in a material change to our financial statements.

For a discussion of our critical accounting estimates, please read Part II, Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 17, 2022. There have been no material changes to the critical accounting estimates previously disclosed in such report other than those discussed below.

Revenue Recognition – Product Sales

We account for revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customer ("Topic 606"), we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product sales are recorded at the net sales price, which includes provisions for the following allowances which are reflected either as a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

Distribution Fees: Distribution fees include distribution service fees paid to the specialty distributors ("SDs") and a specialty pharmacy ("SP") and based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"). Distribution fees are recorded as an offset to product sales based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowance for rebates includes mandated discounts under the Medicaid Drug Rebate Program and TRICARE program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. We estimate for expected utilization of rebates are based on utilization data received from the SDs and SP since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs and SP at a discounted price. The SDs and SP charge back to us the difference between the price initially paid by the SDs and SP and the discounted price paid to the SDs and SP by these entities. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

Co-Payment Assistance: We offer co-payment assistance to commercially insured patients meeting certain eligibility requirement. Co-payment assistance is accrued at the time of product sale to the SDs and SP based on estimated patient participation and average co-pay benefit to be paid per a claim. Our estimated amounts are compared to actual program participation and co-pay amounts paid using data provided by third-party administrators. If actual amounts differ from the original estimates the assumptions being applied are updated and adjustment for prior period accruals will be adjusted in the current period.

Product Returns: Consistent with industry practice, we offer the SDs and SP limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. We do not allow product returns for product that has been dispensed to a patient. As we receive inventory reports from the SDs and SP and have the ability to control the amount of product that is sold to the SDs and SP our estimate of future potential product returns is based on the on-hand channel inventory data and sell-through data obtained from the SDs and SP. In arriving at its estimate, we also consider historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

With the recent launch of FYARRO, it will take some time to accumulate historical actual amounts for the allowances described above. Until then, we are currently accruing for estimated allowances based on historical information for similar marketed IV oncology products.

The total amount deducted from gross product sales for the allowances described above for the three and nine months ended September 30, 2022 was $0.8 million and $1.8 million, respectively.

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 information under this Item.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2022, the end of the period covered by this Quarterly Report. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate.

Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2022.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2022, we implemented a new Enterprise Resource Planning ("ERP") system for financial reporting. This was the only change in our internal controls identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

For discussion of legal proceedings, see Item 1 of Part 1, “Condensed Consolidated Financial Statements - Note 15” in this Quarterly Report.

Item 1A. Risk Factors

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

- We are an early commercial stage biopharmaceutical company, have a limited operating history, have not initiated or completed any large-scale clinical trials, and have a single product approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of FYARRO and any future product candidates.
- Even following approval and commercialization of FYARRO for the advanced malignant PEComa indication and the Private Placement Financing, we will require additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- We are substantially dependent on the success of our lead product candidate, FYARRO. If we are unable to successfully commercialize FYARRO for the advanced malignant PEComa indication or complete development of, obtain approval for and commercialize FYARRO for one or more other indications in a timely manner, our business will be harmed.
- We are dependent on a single-source supplier for the drug product FYARRO, and the loss of such supplier could harm our business.
- If we cannot replicate the results from our earlier preclinical studies and clinical trials of our 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.
- If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary regulatory approvals could be delayed or prevented.
- We have limited resources and are currently focusing our efforts on developing and commercializing FYARRO for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately prove to be more profitable or to have a greater likelihood of success.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or achieve regulatory approval before we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.
- The market opportunities for FYARRO and any other product candidates we may develop in the future, if approved, may be limited to certain smaller patient subsets.
- We may be unable to obtain United States approval for FYARRO for additional indications or other product candidates that we may develop in the future or foreign regulatory approval for FYARRO or other product

candidates that we may develop in the future and, as a result, may be unable to commercialize FYARRO or any future product candidates and our business will be substantially harmed.

- FYARRO is, and any other product candidate we may develop in the future for which we obtain marketing approval for could be, subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we or our collaborators fail to comply with regulatory requirements or if we or our collaborators experience unanticipated problems with FYARRO, or any other product candidate we may develop in the future when and if any of them are approved.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers, key scientific personnel and employees. If we fail to attract and retain such personnel, we may be unable to continue to successfully develop or commercialize our product or any future product candidates or otherwise implement our business plan.
- If we are unable to establish or appropriately scale up our sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product or any future product candidates that obtain regulatory approval.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- If we do not obtain patent term extension for our product or any future product candidates, our business may be materially harmed.
- If any of our third-party manufacturers encounter difficulties in production, our ability to provide adequate supply of FYARRO for patients or for clinical trials or any other product candidate that we may develop in the future, if approved, could be delayed or prevented.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We contract with qualified third parties for the production of FYARRO for commercialization and expect to continue to do so for additional clinical trials. This reliance on third parties, some of which are sole source suppliers, increases the risk that we will not have sufficient quality and quantities of FYARRO or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials and those third parties may not perform satisfactorily.
- Litigation and legal proceedings, including the EOC dispute, may substantially increase our costs and harm our business.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are an early commercial-stage biopharmaceutical company, have a limited operating history and have a single product approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are an early commercial-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have a single product, FYARRO, approved for commercial sale by the FDA in November 2021 and we have generated net product sales of $4.2 million and $10.0 million for the three and nine months ended September 30, 2022, respectively. We continue to incur significant research and development and other expenses related to our ongoing operations. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing biopharmaceutical products.

To date, we have devoted substantially all of our resources to research and development activities, business planning, establishing and maintaining our intellectual property portfolio, preparing for commercialization of FYARRO, hiring personnel, raising capital and providing general and administrative support for these operations. Our Phase 2 registrational study of our drug FYARRO (*nab*-sirolimus) (the “AMPECT trial”) for advanced (metastatic or locally advanced) malignant perivascular epithelioid cell tumors (“PEComa”) has been completed. A rolling New Drug Application (an “NDA”) submission for FYARRO was completed in May 2021, and the U.S. Food and Drug Administration (the “FDA”) accepted our NDA in July 2021 and approved FYARRO for the treatment of advanced malignant PEComa in November 2021. Based on the AMPECT trial and emerging data for FYARRO in other solid tumors with tumor-agnostic Tuberous

Sclerosis Complex 1 and 2 (“*TSC1 & TSC2”)* alterations, and following discussions with the FDA, we opened enrollment for our tumor-agnostic registration-directed Phase 2 trial (“PRECISION 1”) in malignant solid tumors harboring *TSC1 & TSC2* inactivating alterations in the first quarter of 2022. Our other programs are in early preclinical research stages.

We have limited experience managing the manufacture of commercial-scale product through a third party and conducting the sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early commercial-stage biopharmaceutical companies in rapidly evolving fields. We also are transitioning to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception, have only recently begun to generate revenue from product sales and have financed our operations principally through private placements of our convertible preferred stock, federal grants and proceeds from licenses. Our net losses were $14.5 million and $87.1 million for the three months ended September 30, 2022 and 2021, respectively. We had an accumulated deficit of $189.3 million as of September 30, 2022, and $142.7 million as of December 31, 2021. These losses have resulted primarily from costs incurred in connection with research and development activities, costs incurred in connection with commercializing FYARRO and general and administrative costs associated with our operations. We have only one product approved for commercial sale which generated net product sales of $4.2 million for the three months ended September 30, 2022, and we continue to incur significant selling, general and administrative expenses as well as research and development expenses related to our ongoing operations. As a result, we expect to continue to incur significant operating expenses for the foreseeable future due to the cost of commercializing FYARRO, research and development, including identifying and designing additional product candidates and conducting preclinical studies and clinical trials, and the regulatory approval process for FYARRO and any future product candidates. We expect our expenses, and the potential for losses, to increase substantially as we commercialize FYARRO, continue to conduct clinical trials of FYARRO and seek to expand our pipeline. The amount of our future expenses and potential losses is uncertain.

Even if we succeed in commercializing FYARRO for its approved advanced malignant PEComa indication, and if we succeed in receiving regulatory approval for and commercializing FYARRO in additional indications and any future product candidates, we expect to continue to incur significant expenses and increasing operating losses over the next several years and for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital, our ability to fund the commercialization of FYARRO, the development of FYARRO for additional indications and any future product candidates, our ability to achieve and maintain profitability and the performance of our stock.

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

We have one product approved for commercialization in the United States, FYARRO, for the treatment of advanced malignant PEComa, which was approved by the FDA in November 2021 and launched commercially in the United States in February 2022. Our ability to generate substantial product sales sufficient to achieve profitability depends on our ability, alone or with strategic collaboration partners, to obtain the regulatory and marketing approvals necessary to commercialize FYARRO in foreign jurisdictions and to successfully complete discovery, development and eventual commercialization of additional indications or any future product candidates. We do not anticipate generating revenue from product sales significant enough to achieve profitability for the foreseeable future. Our ability to generate future revenue and achieve profitability depends significantly on our ability, or any current or future collaborator’s ability, to achieve several objectives, including, but not limited to:

- demonstrating the safety and efficacy of FYARRO to the satisfaction of the FDA and obtaining regulatory approval for FYARRO for other indications and for any future product candidates, if any, for which there is a commercial market;
- launching and successfully commercializing FYARRO or any product candidates following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;

- maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for FYARRO or any other product candidates we may develop, if approved;
- completing development activities, including clinical trials for FYARRO for *TSC1 & TSC2*, successfully and on a timely basis;
- obtaining additional regulatory and marketing approvals for FYARRO for additional indications;
- our ability to complete investigational new drug application (an "IND") enabling studies and successfully submit INDs or IND supplements or comparable applications, which become effective without any objections by the FDA or comparable regulatory authorities before commencing a clinical trial for any future product candidates;
- establishing and maintaining relationships with contract research organizations ("CROs") and clinical sites for the clinical development of FYARRO in other indications and any other future product candidates that we may develop;
- timely receipt of regulatory approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing or contracting for an efficient and scalable manufacturing process for future product candidates, including obtaining finished products that are appropriately packaged for sale;
- negotiating and maintaining an adequate price for our product or any future product candidates, both in the United States and in foreign countries where our products are commercialized;
- a continued acceptable safety profile following any regulatory approval of product candidates;
- commercial acceptance of product candidates by patients, the medical community and third-party payors;
- obtaining coverage and adequate reimbursement by third-party payors for product candidates;
- satisfying any required post-regulatory approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- entering into and maintaining, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product and any future product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

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

Even after the Private Placement Financing, we will require additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing and planned activities, particularly as we seek additional regulatory approval of FYARRO for additional indications, and the commercialization of FYARRO for its approved indication (PEComa). Our expenses could increase beyond our current expectations if we are required by the FDA, the European Medicines Agency (the "EMA") or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate, or if there are any delays in any of our clinical trials or the development of any future product candidates. Other unanticipated costs may also arise. In addition, even if we obtain regulatory approval for any of other product candidates, including additional indications for FYARRO, we expect to incur

significant commercialization expenses related to sales, marketing, manufacturing and distribution activities and ongoing compliance activities. We cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully commercialize FYARRO for the advanced malignant PEComa indication or complete the development and, if approved, commercialize FYARRO for any other additional indications, or any other product candidates or other indications we may develop. Upon receiving regulatory approval for FYARRO from the FDA in November 2021, we are only permitted to market or promote FYARRO for the advanced malignant PEComa indication, and not for any other indication, or any other product candidate, in the United States. In addition, we will incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of September 30, 2022, we had $183.0 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we believe that our cash, cash equivalents and short-term investments will enable us to fund our planned operating expenses and capital expenditures into 2025. Our estimate as to how long we expect our cash, cash equivalents and short-term investments to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our cash, cash equivalents and short-term investments to fund the commercialization of FYARRO for the advanced malignant PEComa indication, ongoing and planned clinical trials of FYARRO for other indications such as the *TSC1 & TSC2* indications, for manufacturing operations and to fund our other research for other product candidates and development activities, as well as for working capital and other general corporate purposes. Advancing the development of FYARRO and any future product candidate will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments may not be sufficient to fund all of the activities that are necessary to complete the development of FYARRO and any future product candidates.

We will be required to obtain further funding to support our continuing operations through public or private equity offerings, debt financings, third-party funding, marketing and distribution arrangements, collaborations with third parties and licensing arrangements or other sources or a combination of these approaches, which may dilute our stockholders or restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize FYARRO or any other product candidates we may develop in the future, if approved. Adequate additional financing may not be available to us in sufficient amounts or on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder and the possibility of such issuance may cause the market price of our shares to decline. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect the conduct of our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to certain of our technologies or our product candidates, or grant licenses on terms that are not favorable to us, which may have a material adverse effect on our business, operating results and prospects. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to significantly delay, reduce the scope of, suspend or eliminate one or more of our research or development programs, clinical trials or future commercialization efforts.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We have only one product which has completed development and obtained regulatory approval by the FDA for a single indication, FYARRO. We are substantially dependent on the success of FYARRO. If we are unable to successfully commercialize FYARRO for the advanced malignant PEComa indication or complete development of, obtain approval for and commercialize FYARRO for one or more other indications in a timely manner, our business will be harmed.

We have only one commercial product that has launched, completed development and been approved by the FDA, FYARRO, our lead product. Our future success is dependent on our ability to successfully commercialize FYARRO, and to timely and successfully obtain regulatory approval for additional indications for FYARRO. We are investing the majority of our efforts and financial resources to commercialize FYARRO for the advanced malignant PEComa indication and in the research and development of FYARRO for multiple additional indications.

In May 2021, we completed the filing of a rolling NDA for FYARRO to the FDA for approval to treat patients with advanced malignant PEComa, and the FDA accepted our NDA in July 2021 and approved FYARRO for advanced malignant PEComa in November 2021. Our NDA was based on results from our AMPECT trial, involving patients for whom there were no approved therapies in the United States. In November 2019, we announced top-line results from the AMPECT trial, including that the study achieved its primary endpoint of objective response rate (the "ORR") as determined by blinded independent central radiologic review using modified Response Evaluation Criteria in Solid Tumors ("RECIST"). FYARRO will require additional clinical development, expansion of manufacturing capabilities, regulatory approval from foreign regulatory authorities in jurisdictions outside of the United States where we plan to market FYARRO for advanced malignant PEComa and potentially in additional indications, if approved, substantial investment and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote FYARRO for non-PEComa indications, before we receive regulatory approval from the FDA and comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

The success of FYARRO will depend on several factors, including the following:

- the efficacy and safety of FYARRO in a larger number of patients in a non-clinical trial setting that those demonstrated in our clinical trials;
- the effectiveness of our sales, marketing and distribution efforts, particularly during the remote, COVID-19 environment;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for sufficient commercial supplies and additional clinical development of FYARRO;
- the successful launch of commercial sales, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- the timely receipt of regulatory approval for FYARRO from applicable foreign regulatory authorities for advanced malignant PEComa;
- the successful completion of any clinical trials, regulatory approval and commercialization of FYARRO for one or more label expansion indications;
- the extent of any required post-regulatory approval commitments to applicable regulatory authorities;
- the willingness of medical professionals to prescribe and patients to use FYARRO and continue to use FYARRO;
- the availability of coverage and adequate reimbursement and pricing by private and government payors;
- the prevalence and severity of adverse side effects;
- the convenience of prescribing, administrating and initiating patients on FYARRO;
- the potential and perceived value and relative cost of FYARRO;
- the successful and timely completion of the required preclinical studies and clinical trials of FYARRO for current and future indications;
- INDs going into effect with the FDA for our planned and future clinical trials;
- the initiation and successful patient enrollment and completion of additional clinical trials of FYARRO on a timely basis, including our PRECISION 1 trial, a registration-directed Phase 2 study of FYARRO in patients with tumor-agnostic *TSC1 & TSC2* alterations;
- maintaining and establishing relationships with CROs and clinical sites for the development of FYARRO both in the United States and internationally;
- the type, frequency and severity of adverse events in clinical trials;
- demonstrating efficacy and safety profiles that are satisfactory to the FDA and any comparable foreign regulatory authority for regulatory approval obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- a continued acceptable safety profile following our current and future regulatory approval; and
- our ability to compete with other therapies.

In addition to advanced malignant PEComa, based on data from the completed AMPECT trial and our ongoing expanded access program, we have initiated a registration-directed tumor-agnostic Phase 2 study, PRECISION 1, of FYARRO in

patients with malignant solid tumors harboring *TSC1 & TSC2* alterations. We completed a Type B meeting with the FDA in which we discussed the initial trial design. The PRECISION 1 trial is now open for enrollment in the United States and the first patient in the trial was dosed in March 2022. Our product development costs could increase if we experience delays. Significant trial delays also could shorten any periods during which we may have the exclusive right to commercialize FYARRO or allow our competitors to bring products to market before we do, which would impair our ability to successfully capitalize on FYARRO and may harm our business, results of operations and prospects. Events that may result in a delay or unsuccessful completion of additional clinical development of FYARRO include, among other things:

- unexpectedly high rate of patients withdrawing consent or being lost to follow-up;
- feedback from the FDA and foreign regulatory authorities, institutional review boards ("IRBs"), or a data safety monitoring board, or results from clinical trials that might require modification to a clinical trial protocol;
- imposition of a clinical hold by the FDA or other regulatory authorities, a decision by the FDA, other regulatory authorities, IRBs or us, or a recommendation by a data safety monitoring board to suspend or terminate trials at any time for safety issues or for any other reason;
- deviations from the trial protocol by clinical trial sites and investigators or failure to conduct the trial in accordance with regulatory requirements;
- failure of third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- delays in the testing, validation, manufacturing and delivery of FYARRO to customers or the clinical trial sites;
- delays caused by patients dropping out of a trial due to side effects, disease progression or other reasons;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse drug reactions;
- failure to demonstrate the efficacy of FYARRO in this clinical trial;
- changes in government regulations or administrative actions or lack of adequate funding to continue the trials; or
- business interruptions resulting from geo-political actions, including war and terrorism, such as the Russia-Ukraine conflict, or natural disasters and public health epidemics, such as the COVID-19 pandemic.

An inability by us to timely complete clinical development could result in additional costs to us or impair our ability to generate substantial product sales or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of our current or any future collaborators. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize FYARRO for multiple indications, which would materially harm our business. If we do not receive regulatory approvals for FYARRO in additional indications or for other product candidates, we may not be able to continue our operations.

In addition to FYARRO, our prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates other than FYARRO. Prior to initiating clinical trials with product candidates, we will need to file an IND or similar application to the FDA or regulatory authorities in other jurisdictions. We may not be able to file future INDs for product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory clearance for our trials may prevent us from developing product candidates on a timely basis, if at all. A product candidate can unexpectedly fail at

any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical studies or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other product candidates we may develop will depend on many factors, including the following:

- generating sufficient preclinical data to support the initiation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct preclinical studies and clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- generating sufficient safety and efficacy data to warrant continued development and which are satisfactory to the FDA or any other regulatory authority for marketing approval.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from any additional product candidates beyond FYARRO for advanced malignant PEComa.

FYARRO or any other product candidates we may develop in the future may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success, which would limit the revenue that we generate from our sales.

Even though FYARRO has been approved for advanced malignant PEComa, and even if any other product candidates that we may develop in the future receive regulatory approval, such approved product candidates may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including, among others:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities or the willingness of patients to pay out-of-pocket in the absence of third-party payor coverage;
- the availability of an approved product candidate for use as a combination therapy;
- the prevalence and severity of any adverse effects associated with any approved product candidate;
- any restrictions on the use of our product candidates together with other medications;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

Even though FYARRO is approved for advanced malignant PEComa, it may never achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, and we may not generate or derive sufficient revenue from that product and our financial results could be negatively impacted. Before granting reimbursement approval, healthcare payors

may require us to demonstrate that our product candidates, in addition to treating target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful.

The market opportunities for FYARRO and any other product candidates we may develop in the future, if approved, may be limited to certain smaller patient subsets.

Cancer therapies are sometimes characterized by line of therapy (first-line, second-line, third-line, etc.) and the FDA often approves new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. FYARRO for advanced malignant PEComa has been approved as a first-line therapy. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor- targeted therapies, more invasive forms of surgery and new technologies. Our completed and planned clinical trials for FYARRO are with patients who may have received one or more prior treatments. There is no guarantee that product candidates that we develop, even if approved, would be approved for first-line or second-line therapy and, prior to any such approvals, we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Our projections of addressable patient populations that may benefit from treatment with our product or any future product candidates are based on our estimates, which may prove to be incorrect. Additionally, the potentially addressable patient population for FYARRO and any future product candidates may be limited or may not be amenable to treatment with such product. Regulatory approval may limit the market of a product candidate to target patient populations when such biomarker-driven identification and/or highly specific criteria related to the stage of disease progression are utilized. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we develop could be significantly diminished and have an adverse material impact on our business.

Even if we obtain significant market share for any approved product, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

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

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

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products, which would include FYARRO and any other product candidate we may develop in the future for which we may obtain regulatory approval. Market acceptance and sales of FYARRO or any other product candidates we may develop in the future for which we obtain regulatory approval will depend on reimbursement policies and may be affected by healthcare reform measures. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance. Third-party payors decide which drugs they will pay for and establish reimbursement levels. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services (“HHS”). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS’s decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor’s determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. Factors that payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under the health plan; (ii) safe,

effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs such as FYARRO. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (an "ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, FYARRO or any other product candidate we may develop in the future may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for FYARRO or any other product that we may commercialize and, if reimbursement is available, what the level of reimbursement will be.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to prescription drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024 (the "American Rescue Plan"), the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such laws once we begin commercialization for FYARRO or, after obtaining regulatory approval, any of our other product candidates that we may develop in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize FYARRO or any other product candidates that we may develop in the future if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as FYARRO or any other product candidates that we may develop in the future if approved. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives regulatory approval. To obtain favorable reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of FYARRO or any other product candidate that we may develop in the future if approved to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for FYARRO or any other product candidates that we may develop in the future if approved. Accordingly, in markets outside the United States, the reimbursement for FYARRO or any other products that we may develop in the future and receive regulatory approval for may be unavailable or reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If reimbursement is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

If we are unable to establish or sustain coverage and adequate reimbursement for FYARRO or any other product candidates that we may develop in the future if approved from third-party payors, the adoption of FYARRO or those other products if approved, the prices of FYARRO or those other products if approved and sales revenue from FYARRO or those other products if approved will be adversely affected, which, in turn, could adversely affect the ability to market or sell FYARRO or any other product candidates that we may develop in the future, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize FYARRO or any other products candidates that we may develop in the future if approved. It is unclear what effect these legislative, executive, and administrative actions and any future healthcare measures and agency rules will have on the number of covered individuals. Even if favorable coverage and reimbursement status is attained for FYARRO or one or more product candidates that we may develop in the future for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We may not be able to obtain FDA approval of any future NDA for FYARRO or any other product candidates we may develop in the future.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to FYARRO and any other product candidate that we may develop in the future are subject to extensive regulation in the United States. Prior to the recent approval of our NDA for FYARRO for advanced malignant PEComa, we had not submitted an application for approval or obtained FDA approval for any product.

Approval of an NDA is not guaranteed. The approval process is expensive and uncertain and may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Data are subject to varying interpretation and the FDA may not agree that our clinical data support that any of our product candidates are safe and effective for the proposed therapeutic use. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that require us to repeat or perform additional preclinical studies or clinical trials or generate additional chemistry, manufacturing and controls data, including drug product stability data. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate, and may ultimately approve the product for narrower indications or with unfavorable labeling that would impede our commercialization of the drug.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed.

Failure to obtain marketing approval in international jurisdictions would prevent FYARRO and any other product candidates we may develop in the future from being marketed abroad.

In order to market and sell our products in the European Union and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

A variety of risks associated with marketing FYARRO and any other product candidates we may develop in the future internationally could affect our business.

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

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the United States Foreign Corrupt Practices Act (“FCPA”) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

In addition, the conflict between Russia and Ukraine could lead to disruption, instability and volatility in global markets and industries that could negatively impact our operations. The U.S. government and other governments in jurisdictions in which we may operate in the future have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, business partners or customers.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

The preclinical studies and clinical trials for FYARRO or any other product candidates that we may develop in the future may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results, which would prevent, delay, or limit the scope of development, regulatory approval and commercialization.

Before obtaining regulatory approval from the EMA or other foreign regulatory authorities for the sale of FYARRO for advanced malignant PEComa or any additional indications that we may seek approval for, or other product candidates when approved, we, among other requirements, must complete preclinical development and extensive clinical trials to demonstrate with substantial evidence the safety and efficacy of such product or other product candidates. Each product or product candidate must demonstrate an adequate risk versus benefit profile in our intended patient population and for our intended use. Drug product must also be manufactured and tested in accordance with regional regulatory requirements which may differ from region to region. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is inherently uncertain. A failure of one or more preclinical studies or clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies in the biopharmaceutical industry that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their products. Our current or future clinical trials may not ultimately be successful or support further clinical development of FYARRO or any other product candidates we may develop in the future.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or our ability to commercialize FYARRO for additional indications or for any other product candidates we may develop in the future, including:

- receipt of feedback from regulatory authorities that require us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- clinical trial sites or our CRO failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- delays due to the recent COVID-19 pandemic, including starting any clinical trials for other indications or programs.

For instance, we do not know whether FYARRO will perform in current or future clinical trials for additional indications as it has performed in preclinical studies or prior clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Additionally, while we are aware of several other approved and clinical-stage mTOR inhibitors being developed by multiple other companies, to our knowledge, there are no mTOR inhibitors approved specifically for the treatment of advanced malignant PEComa other than FYARRO. As such, the development of FYARRO and our stock price may be impacted by inferences, whether correct or not, that are drawn between the success of our product and those of other companies' mTOR inhibitors. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety and efficacy results, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our products may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our products. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market FYARRO for additional indications or for any other product candidates we may develop in the future. If we are required to conduct additional clinical trials or other testing of our product beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may (i) incur unplanned costs, (ii) be delayed in seeking and obtaining regulatory approval for respective indications, if we receive such approval at all, (iii) receive more limited or restrictive regulatory approval for respective indications, (iv) be subject to additional post-marketing testing requirements or (v) have the drug removed from the market after obtaining regulatory approval. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit their commercial potential.

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

If FYARRO or any other product candidates that we may develop in the future is associated with serious adverse events or other undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to conduct additional studies to further evaluate the product candidates' safety, interrupt, delay or abandon their development or halt clinical trials or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in a more restrictive label, delay or denial of regulatory approval or potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate, could substantially increase the costs of commercializing our product(s) and significantly impact our ability to successfully commercialize our product(s) and generate revenues, and may harm our business, financial condition and prospects significantly. For example, in our AMPECT trial of FYARRO, most treatment-related adverse events were mild or moderate, with the most commonly reported adverse events being anemia, edema, infections, mucositis, pain, nail changes, vomiting, thrombocytopenia, hypertension and nausea. Treatment-related adverse events in our other oncology and PAH trials of FYARRO included thrombocytopenia, diarrhea, fatigue, mucosal inflammation, nausea, anemia, and rash. Additionally, in our first- in-human study of FYARRO in solid tumors, one patient died of dyspnea which was deemed possibly related to FYARRO.

Patients in our completed and planned clinical trials may in the future suffer other significant adverse events or other side effects not observed or anticipated based on our preclinical studies or previous clinical trials. FYARRO or other product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, FYARRO is being studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with FYARRO or our other product candidates that we may develop in the future may also be undergoing surgical, radiation and/or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients enrolled in our FYARRO clinical trials will die or experience major adverse clinical events either during the course of our clinical trials or after such trials, which has occurred in the past.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable regulatory authorities or an institutional review board may suspend or terminate clinical research at any time for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development.

Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, for FYARRO for advanced malignant PEComa, or if FYARRO receives regulatory approval for any other indication, or if any other product candidate that we may develop in the future if any of our product candidates obtains regulatory approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to (i) conduct additional clinical safety trials, (ii) add additional contraindications, warnings and precautions to the drug label, (iii) significantly restrict the use of the product, (iv) change the way the product is distributed or administered, (v) implement a risk evaluation and mitigation strategy, or create a medication guide outlining the risks of such side effects for distribution to patients, or (vi) suspend or withdraw the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

Results from early preclinical studies and clinical trials of FYARRO or other product candidates that we may develop in the future are not necessarily predictive of the results of later preclinical studies and clinical trials of FYARRO or such other product candidates. If we cannot replicate the results from our earlier preclinical studies and clinical trials in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize FYARRO in additional indications or any future product candidates.

Any results from early preclinical studies and clinical trials of FYARRO or other product candidates that we may develop in the future 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 according to our current development timeline,

the results from such preclinical studies and clinical trials 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 FDA or EMA approval.

Additionally, some of our ongoing, planned and future clinical trials may utilize an open-label study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates when studied in a controlled environment with a placebo or active control.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. The preliminary data is based on a preliminary analysis of then available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report tumor responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, FYARRO in other indications or any other product candidates that we may develop in the future may be harmed, which could harm our business, financial condition, results of operations and prospects.

Adverse results of clinical trials conducted by third parties investigating the same product candidates as us in different territories could adversely affect our development of such product candidate.

Lack of efficacy, adverse events, undesirable side effects or other adverse results may emerge in clinical trials conducted by third parties investigating our approved product or the same product candidates as us in different territories for the same or different indications. For example, we may in the future enter into collaborations for the development and commercialization of FYARRO in certain foreign jurisdictions. As part of these collaborations, we may grant such

collaboration partners with the right to develop and commercialize the same compounds licensed to us, including FYARRO, in such foreign jurisdictions. As a result, we may not have control over clinical trials or development programs of such third parties that we may collaborate with in the future, and any adverse findings or unexpected side effects from such third party's conduct of clinical trials could adversely affect our development and commercialization of FYARRO or the viability of FYARRO as a product candidate. We may be required to report these adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of FYARRO.

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

We may not be able to initiate or continue clinical trials for FYARRO or any future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Orphan indications, in particular, have small populations, and it may be difficult for us to locate and enroll sufficient patients in trials for orphan-designated indications. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to identify and enroll eligible patients for clinical trials may be limited or may result in slower enrollment than we anticipate. For instance, patients for our trials for the *TSC1 & TSC2* study are screened using genomic information to identify alterations in the *TSC1 & TSC2* genes and utilizing such criteria and/or certain highly specific criteria related to the cancer sub-types may limit patient populations eligible for our clinical trials. In particular, because we are focused on patients with specific genetic alterations for certain of our development programs, our ability to enroll eligible patients may be limited or may result in slower enrollment than anticipated. For example, with respect to FYARRO, we cannot be certain how many patients will harbor the *TSC1 & TSC2* alterations that FYARRO is designed to target or that the number of patients enrolled for each alteration will suffice for regulatory approval and inclusion of each such alteration in the approved label. 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, furthering the difficulty in identifying patients with the targeted genetic alterations for our clinical trials. If our strategies for patient identification prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for FYARRO.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates.

Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment for one or more of our trials. Patient enrollment and retention for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol or as mandated by regulatory agencies;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- the ability to recruit clinical study investigators with the appropriate competencies and experience;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- patient referral practices of physicians;
- the ability to obtain and maintain patient consents;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., the COVID-19 pandemic).

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Furthermore, any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, there is a risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials. As a result, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance.

We expect to develop FYARRO and potentially other product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop FYARRO and potentially other product candidates, in combination with one or more currently approved or unapproved therapies to treat cancer or other diseases. Patients may not be able to tolerate FYARRO or any of future product candidates in combination with other therapies or dosing of FYARRO in combination with other therapies may have unexpected consequences. Even though FYARRO has received FDA approval for advanced malignant PEComa, and even if FYARRO receives regulatory approval for additional indications, if any of our product candidates that we develop in the future were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with such product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates, the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions requiring additional clinical trials, or our own products being removed from the market or being less successful commercially.

We may also evaluate future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain regulatory approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with FYARRO or any future product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop. These unapproved therapies face the same risks described with respect to product candidates currently in development, including serious adverse effects and delays in their clinical trials. In addition, other companies may also develop their products or product candidates in combination with the unapproved therapies with which we are developing our product candidates for use in combination. Any setbacks in these companies' clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of our product candidates.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited resources and are currently focusing our efforts on developing and commercializing FYARRO for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately prove to be more profitable or to have a greater likelihood of success.

We are currently focusing our resources and efforts on developing and commercializing FYARRO for particular indications. As a result, because we have limited financial and managerial resources, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research and development activities for FYARRO and other programs may not yield any commercially viable drugs. If we do not accurately evaluate the completed clinical trial data, likelihood of future clinical

trial success, commercial potential or target markets for FYARRO or any of our other product candidates that we may develop in the future, we may relinquish valuable rights to that product candidate or program through collaboration, licensing or other strategic or royalty arrangements in cases in which we would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or achieve regulatory approval before we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with FYARRO for advanced malignant PEComa or for any additional indications we may seek approval for, and for any other product candidates that we may develop in the future, if approved. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our products may need to compete with drugs that physicians currently use to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

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

Other than FYARRO, we are not aware of any FDA or EMA approved products indicated specifically for the treatment of advanced malignant PEComa. Patients with malignant PEComa commonly receive chemotherapy regimens and currently mTOR inhibitors including sirolimus, everolimus, and temsirolimus are recommended in the National Comprehensive Cancer Network (the “NCCN”) guidelines for treatment of malignant PEComa based on published retrospective data. Following FDA approval, FYARRO was added to the NCCN guidelines as the only preferred regimen for treatment of malignant PEComa. For tumor agnostic *TSC1 & TSC2* inactivating alterations, there are no existing FDA or EMA approved products indicated for such use. If FYARRO receives additional regulatory approval for these *TSC1 & TSC2* indications, it may face competition from other drug candidates in clinical trials that target the mTOR pathway. These may include dual mTORC1/2 inhibitors in clinical trials or next generation mTOR inhibitors in development. Any potential competitors may have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than us. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in the field before 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, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop and commercialize. Our competitors also may obtain regulatory approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. Our approved product, or product candidates we may develop in the future which achieve regulatory approval, may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates

obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of FYARRO or any product candidates we may develop in the future, if approved, could be adversely affected.

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

As product candidates progress through preclinical studies and clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce alternative formulations or dosage forms of FYARRO in additional clinical trials for other indications. Such material changes will require regulatory approval before implementation and carry the risk that they will not achieve these intended objectives. Any of these changes could cause FYARRO and any other product candidate that we may develop in the future to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize FYARRO or any other product candidates that we may develop in the future, if approved, and generate revenue.

We may not be successful in growing our product pipeline through acquisitions and in-licenses.

We believe that accessing external innovation and expertise is important to our success; and while we plan to leverage our leadership team's prior business development experience as we evaluate potential in-licensing and acquisition opportunities to further expand our portfolio, we may not be able to identify suitable licensing or acquisition opportunities, and even if we do, we may not be able to successfully secure such licensing and acquisition opportunities. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These 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 may also be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully license or acquire additional product candidates to expand our portfolio, our pipeline, competitive position, business, financial condition, results of operations, and prospects may be materially harmed.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have a material adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims might be brought against us by patients, healthcare providers, or others selling or otherwise coming into contact with FYARRO or any other product candidates that we may develop in the future. For example, we may be sued if FYARRO or any other product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend against them, we could incur substantial liabilities. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our (or third-party) manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. Although we have obtained product liability insurance coverage, our insurance coverage may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain or maintain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could also cause our stock price to decline.

The recent global COVID-19 outbreak has affected and is expected to continue to affect our business and operations.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development activities. To date, the COVID-19 pandemic has caused significant disruptions to the United States and global economy. Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of our product candidates. The COVID-19 pandemic caused us to modify business practices (including but not limited to curtailing or modifying employee travel and participation in meetings, events, and conferences, and curtailing or modifying our clinical trials). For example, we have experienced, and continue to experience, some clinical development disruptions due to the pandemic, including closures at certain lab facilities, which have led, and continue to lead, to longer than anticipated clinical development times. In addition, our clinical trials have been, and may continue to be, affected by the closure of offices, or country borders, among other measures being put in place around the world. Restrictions on the ability to travel and conduct face-to-face meetings, as well as constraints surrounding hospital resources, infrastructure, staff and other resources, can also make it more difficult to enroll new patients in ongoing or planned clinical trials.

As a result of the evolving COVID-19 pandemic, we have experienced and expect to continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- continued delays or difficulties in enrolling and retaining and adequate number of patients in our clinical trials;
- continued delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations (“CMOs”) due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, including as a result of the COVID-19 pandemic;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require changes in the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays to our sourced discovery and clinical activities; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The extent of the impact of the COVID-19 pandemic on our future liquidity and operational performance will depend on certain developments, including the duration and spread of further outbreaks, the availability, acceptance and effectiveness of vaccines, the impact on our clinical trials, patients, and collaboration partners, and the effect on our suppliers.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

If the FDA does not conclude that a product candidate and/or new indications satisfy the requirements under the 505(b)(2) regulatory pathway, or if the requirements for such product candidate and/or new indications under Section 505(b)(2) are not as we expect, the approval pathway for such product candidates and/or new indications may take longer, cost more or entail greater complications and risks than anticipated, which may delay or prevent the approval of a product candidate and/or new indications for commercial use.

We submitted a Section 505(b)(2) NDA to the FDA in May 2021 for FYARRO for the treatment of advanced malignant PEComa, and the FDA approved the NDA in November 2021. We may not be successful in obtaining FDA approval under 505(b)(2) regulatory pathway for other indications or product candidates that we may develop.

Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA is not required to meet the PDUFA goal date, and the FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval. Moreover, even if any new indication or product candidate is approved under the Section 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which we may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

We may be unable to obtain United States approval for FYARRO for additional indications or other product candidates that we may develop in the future or foreign regulatory approval for FYARRO or such product candidates that we may develop in the future and, as a result, may be unable to commercialize FYARRO or other product candidates and our business will be substantially harmed.

FYARRO and the other product candidates that we may develop in the future are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. we cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon numerous factors, including the type, complexity and novelty of the product candidate. The standards that the FDA and our foreign counterparts use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review. 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. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Additionally, as of March 18, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. In February 2022, the FDA announced that it will resume routine domestic surveillance inspections. The FDA also announced proceeding with previously planned foreign surveillance inspections that have received country clearance and are within Level 1 or Level 2 COVID-19 travel recommendation of the Centers for Disease Control and Prevention (the "CDC"); otherwise, the inspection would be rescheduled, with the anticipated goal of resuming foreign prioritized inspections in April 2022. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval.

Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy ("REMS") plan as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for FYARRO for additional indications or other product candidates that we may develop, we will be unable to generate product revenue, and our business will be substantially harmed.

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. 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. Even though FYARRO has been approved by the FDA, and even if we eventually complete clinical testing and receive approval for FYARRO in additional indications or for any other product candidates that we may develop in the future, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. We have not obtained regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval.

Further, regulatory approval may be delayed for reasons beyond our control. For example, a United States federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, or the current diversion of resources to handle the COVID-19 public health emergency and pandemic may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to obtain regulatory approval for our product candidates. In addition, the impact of COVID-19 may cause the FDA to allocate additional resources to product candidates focused on treating related illnesses, which could lead to longer approval processes for our product candidates. Finally, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any of our NDAs.

Applications for any future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude us from obtaining regulatory approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for our proposed indication is acceptable;

- the FDA, EMA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests for our product candidates, if required; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in us failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

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

Our clinical trials have been and may in the future be undertaken in the United States. We may choose to conduct additional clinical trials internationally as well. For example, we may conduct our PRECISION 1 trial of FYARRO in the United States, Europe and other countries. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for regulatory approval in foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Brexit and uncertainty in the regulatory framework as well as future legislation in the United Kingdom, European Union, and other jurisdictions can lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. Uncertainty in the regulatory framework could also result in disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients and finished product. Such a disruption could create supply difficulties for ongoing clinical trials. The cumulative effects of the disruption to the regulatory framework, uncertainty in future regulation, and changes to existing regulations may increase our development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

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.

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

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

Following Brexit, to the extent we conduct any operations in the United Kingdom, we will be subject to applicable regulatory requirements in the United Kingdom. Although the United Kingdom is no longer a member of the European Union, European Union law remains applicable in Northern Ireland. There are a number of new marketing authorization routes available in the United Kingdom, Great Britain (England, Scotland and Wales) or Northern Ireland, in addition to the national procedure. As with the European Union position, a company can only start to market a medicine in the United Kingdom once it has received a marketing authorization. The main legislation that applies to clinical trials in the United Kingdom is the UK Medicines for Human Use (Clinical Trials) Regulations 2004, which transposes the Clinical Trials Directive into domestic law. Consequently, the requirements and obligations that relate to the conduct of clinical trials in the United Kingdom currently remain largely aligned with the European Union position. It is unclear how future regulatory regime in the United Kingdom will impact regulations of products, manufacturers, and approval of product candidates in the United Kingdom. In the immediately foreseeable future, the United Kingdom regulatory approval process is likely to remain similar to that applicable in the European Union, albeit that the processes for applications will be separate. Longer term, the United Kingdom is likely to develop its own legislation that diverges from that in the European Union.

FYARRO is, and any other product candidate we may develop in the future for which we obtain marketing approval for could be, subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we or our collaborators fail to comply with regulatory requirements or if we or our collaborators experience unanticipated problems with FYARRO, or any other product candidate we may develop in the future when and if any of them are approved.

FYARRO is, and any other product candidate we may develop in the future for which we obtain marketing approval could be, subject to a comprehensive regulatory scheme, which includes the regulation of manufacturing processes, post-approval clinical data, labeling, advertising, marketing, distribution and promotional activities for such product, by the FDA and other regulatory authorities. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. For example, the FDA may require the submission of a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices (“cGMPs”), good laboratory practices (“GLPs”) and good clinical practices (“GCPs”) for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

FYARRO is, and if marketing approval of any other product candidate we may develop in the future is granted may be, subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could involve requirements for, among other things, a medication guide, special training for prescribers and dispensers, and patient registries. As a condition of the approval of the NDA for FYARRO, we are required to conduct certain post-marketing requirements (“PMR”) and/or post-marketing commitments (“PMC”). If we fail to comply with the PMR and/or PMC, the FDA may take enforcement actions, which may include, among other things, the issuance of a Warning Letter and assessing civil monetary penalties. The product may also be deemed misbranded.

FYARRO does, and if any other product candidate that we may develop in the future receives marketing approval they may, have a label that limits their approved uses, including more limited subject populations, than we request, and regulatory authorities may require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, 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, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of products to ensure products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers’ communications regarding off-label use and if we do

not market our prodrug products, if any, for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to a number of actions and penalties, including warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences.

We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may have negative consequences, including:

- adverse inspection findings;
- additional warnings or otherwise restrict the product's indicated use, label, or marketing;
- restrictions on our FYARRO products, distribution, manufacturers or manufacturing processes;
- issuance of warning letters, safety alerts, dear-healthcare-provider letters, press releases or other communications containing warnings regarding the product that would result in adverse publicity;
- voluntary or mandatory product recalls and publicity requirements or withdrawal of FYARRO from the market;
- suspension or withdrawal of marketing or regulatory approvals or other permits or voluntary;
- product seizures, detentions or import bans;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- requirement to establish or modify a REMS;
- requirement to conduct post-marketing studies or surveillance;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- refusal to approve pending applications or supplements to approved applications that we submit and other delays;
- delays in or the rejection of approvals of additional indications for FYARRO;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on, or the suspension or termination of, ongoing or planned trials;
- fines, restitution or disgorgement of profits or revenue;
- reputational harm;
- refusal of government contracts or future orders under existing contracts, exclusion from participation in federal health care programs; or
- injunctions or the imposition of civil or criminal penalties, including False Claims Act liability.

The holder of an approved NDA or comparable regulatory approval must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process and the FDA or comparable foreign regulatory authority may refuse to approve pending applications or supplements to approved applications filed by us.

The occurrence of any event or penalty described above may inhibit our ability to commercialize FYARRO and any other product candidates that we may develop in the future, if approved, and generate revenue. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of the company and our operating results will be adversely affected.

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

If we are found to have improperly promoted off-label uses of FYARRO or any other product candidate that we may develop in the future, if approved, we may become subject to significant liability. The FDA and other regulatory agencies, including the U.S. Department of Justice, strictly regulate the post-approval marketing and promotional claims that may be made about prescription products, such as for FYARRO. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. As such, we may not promote our products for indications or uses for which they do not have approval. For example, physicians may, in their practice of medicine, use drug products for their patients in a manner that is inconsistent with the approved label. If we, or any of our contractors or agents acting on behalf of us, are found to have promoted such off-label uses, we may become subject to significant liability. The United States federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of FYARRO and any other product candidate that we may develop in the future, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are required by the FDA to obtain approval of a companion diagnostic product in connection with approval of any future product candidates or new indication that we may develop, and if we fail to obtain or face delays in obtaining FDA approval of such companion diagnostic product, we will not be able to commercialize such product candidate intended for use with such companion diagnostic product and our ability to generate revenue from such product candidate will be materially impaired.

In connection with the development of any future product candidates or new indications we may develop or work with collaborators to develop or obtain access to companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our programs. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of any future product candidates or new indication we may develop. To be successful in developing and commercializing such product candidate in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has required marketing approval of all companion diagnostic tests for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of our current diagnostics and any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genetic alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any future product candidate or new indication that we may develop, whether before or concurrently with approval of such product candidate, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future issuances from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our 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 product candidates, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for any future product candidate or new indication, or experience delays in doing so, the development of such product candidate may be adversely affected, the product candidate may not obtain marketing approval, and we may not realize the full commercial potential of such product candidate after obtaining marketing 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 any such future product candidate 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 any such future product or new indication. or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of any such future product candidate we may develop.

A Fast Track or Breakthrough Therapy designation for FYARRO may not lead to a faster development or review process, or we may be unable to maintain or effectively utilize such a designation. We may also seek additional Fast Track designations from the FDA for FYARRO or any of our other product candidates. Even if one or more of our product candidates receive Fast Track designation, we may be unable to obtain or maintain the benefits associated with the Fast Track designation.

In March 2022 and October 2018, we announced that the FDA granted Fast Track designation for FYARRO for the investigation of the treatment of adult and adolescent patients with malignant solid tumors harboring *TSC1 & TSC2* alterations and of patients with advanced malignant PEComa, respectively. While the FDA granted us Priority Review of our NDA for FYARRO in patients with advanced malignant PEComa, there is no guarantee that this Fast Track designation for the *TSC1 & TSC2* alterations will qualify for or that we will be able to take advantage of the expedited review procedures or that we will ultimately obtain regulatory approval of FYARRO in other indications. Even though we received this Fast Track designation in the past, we may not experience a faster development process, review or approval compared to conventional FDA procedures for other indications for FYARRO. We may also seek Fast Track designation for additional cancer indications or other diseases, and we may not be successful in securing such additional designation or in expediting development if such designations were received. Even if we receive Fast Track designation for additional cancer indications, the FDA may withdraw such Fast Track designation if it believes that the Fast Track designation is no longer supported by data from our clinical development program.

Fast Track designation is designed to facilitate the development and expedite the review of therapies intended for the treatment of a serious or life-threatening condition which demonstrate the potential to address unmet medical needs for the condition. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If FYARRO for the investigation for the treatment of patients with malignant solid tumors harboring *TSC1 & TSC2* alterations, or FYARRO for any other indication or any other product candidates that we may develop in the future that receives Fast Track designation, does not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. The FDA may withdraw any Fast Track Designation at any time. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures and we may not experience a faster development process, review or approval compared to conventional FDA procedures.

In December 2018, we announced that the FDA granted Breakthrough Therapy designation for FYARRO for the treatment of patients with advanced malignant PEComa. We may also seek a Breakthrough Therapy designation for FYARRO for various cancer indications or other diseases. Breakthrough Therapy designation is for a product candidate 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 product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request the FDA to designate our product candidate as a Breakthrough Therapy at the

time of, or any time after, the submission of an IND for the product candidate. For product candidates that have been designated as a Breakthrough Therapy, the FDA may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the product candidate; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product candidate to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

The FDA has broad discretion in determining whether to grant a Fast Track or Breakthrough Therapy designation for a drug. Obtaining a Fast Track or Breakthrough Therapy designation does not change the standards for product approval but may expedite the development or approval process. There is no assurance that the FDA will grant either such designation for any other indication or product candidate that we may pursue. Even if the FDA does grant either such designation, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that FYARRO will receive regulatory approval in the United States in other indications.

We may not be able to obtain or maintain orphan drug designation or obtain or maintain orphan drug exclusivity for FYARRO or any future product candidates and, even if we do, such exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is 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 greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for FYARRO in additional indications or for any future product candidates.

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. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if orphan drug designation is granted, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain regulatory approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, that the orphan drug exclusivity may not effectively protect an approved product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

We received orphan drug designation from the FDA for FYARRO for the treatment of advanced malignant PEComa. We may be unable to obtain orphan drug designation for any other indication or regulatory approval for FYARRO for any other orphan population, or we may be unable to successfully commercialize FYARRO for such orphan population due to risks that include:

- the orphan patient populations may change in size;

- there may be changes in the treatment options for patients that may provide alternative treatments to FYARRO;
- the development costs may be greater than projected revenue of drug sales for the orphan indications;
- the regulatory agencies may disagree with the design or implementation of our clinical trials;
- there may be difficulties in enrolling patients for clinical trials;
- FYARRO may not prove to be efficacious in the respective orphan patient populations;
- clinical trial results may not meet the level of statistical significance required by the regulatory agencies; and
- FYARRO may not have a favorable risk/benefit assessment in the respective orphan indication.

If we are unable to obtain regulatory approval for FYARRO in any other orphan population for which we obtain orphan drug designation or we are unable to successfully commercialize FYARRO for such orphan population, it could harm our business prospects, financial condition and results of operations.

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

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for future product candidates. Under the accelerated approval provisions in the FDA, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that generally provides a meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

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

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of FYARRO for advanced malignant PEComa outside the United States and for any additional indications that we may seek approval for, or any product candidates that we may develop in the future. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action,

either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the former Trump administration to repeal or replace certain aspects of the ACA. In June 2021, the Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this decision and other healthcare reforms will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for FYARRO or any other product candidates that we may develop if the future, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require a pharmaceutical manufacturer to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In response to this executive order, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Implementation of cost containment measures or other healthcare reforms that affect the

pricing and/or availability of drug products may impact our ability to generate revenue, attain or maintain profitability, or commercialize products for which we may receive regulatory approval in the future.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act"), was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

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

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other jurisdictions. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Additionally, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (the "GDPR"), which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions and imposes substantial obligations upon companies and new rights for individuals. Failure to comply with the GDPR and the applicable national data protection laws of the European Union Member States may result in fines up to €20.0 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we may process, and we may be required to put in place additional mechanisms in an effort to comply with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union.

Finally, state and foreign laws may apply generally to the privacy and security of information we maintain, and may differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Privacy Act of 2018 (the "CCPA"), which took effect on January 1, 2020, gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. In addition, the CCPA (a) allows enforcement by the California Attorney General, with fines set at $2,500 per violation (i.e., per person) or $7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. While it exempts some data regulated by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and certain clinical trials data, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Some observers note that the CCPA 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.

Inadequate funding for the FDA, the Securities and Exchange Commission ("SEC") and other government agencies 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. 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, in recent years, including in 2018 and 2019, the United States government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. 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. Separately, in response to the COVID-19 pandemic, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. In February 2022, the FDA announced that it will resume routine domestic surveillance inspections. The FDA also announced proceeding with previously planned foreign surveillance inspections that have received country clearance and are within the CDC's Level 1 or Level 2 COVID-19 travel recommendation; otherwise, the inspection would be rescheduled, with the anticipated goal of resuming foreign prioritized inspections in April 2022. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. While the FDA indicated that it will consider alternative methods for inspections and exercise discretion on a case-by-case basis to approve products based on a desk review, if a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities on a timely basis, 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. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with other United States healthcare laws and compliance requirements, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. Further, our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to

bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;
- the federal HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance effort;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding certain payments and other transfers of value made to covered recipients in the previously year, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; our failure to submit required information timely, accurately, and completely may result in significant civil monetary penalties and may increase our liability under other federal laws or regulations; and
- additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state

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

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions or safe harbors, it is possible that some of our activities, including those of our contractors or agents who conduct business for or on behalf of us, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

If we were to grow our business and expand our sales organization or rely on distributors outside of the United States, we would be at increased risk of violating these laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraud, misconduct or other improper activities. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with federal and state health care fraud and abuse laws and regulations and similar foreign fraudulent misconduct laws; and accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, certain customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending our self or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

If we or any contract manufacturers and suppliers we engage fails 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 our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures, the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes, the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. The operations of our contractors may involve the use of hazardous and flammable materials, including chemicals and biological materials, and accordingly may 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, including any contamination at our current or past facilities and at third-party facilities, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees are employed by the government and would be considered foreign officials under the FCPA, and often the purchasers of pharmaceuticals are government entities; therefore, our dealings with these doctors, hospital employees and purchasers are subject to regulation under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, collaborators, or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, United States export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by United States sanctions. For example, the U.S. government and other governments in jurisdictions in which we may operate in the future have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls in connection

with the conflict between Russia and Ukraine. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, business partners or customers.

If we fail to comply with export and import regulations, and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Further, with rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs that result in increased global clinical trial costs as a result of international transportation of clinical drug supplies, as well as the costs of materials and products imported into the United States. Tariffs, trade restrictions or sanctions imposed by the United States or other countries, including as a result geopolitical tension, such as a deterioration in the relationship between the United States and China or escalation in conflict between Russia and Ukraine, including any additional sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries against governmental or other entities in Russia, could increase the prices of our and our collaboration partners' drug products, affect our and our collaboration partners' ability to commercialize such drug products, or create adverse tax consequences in the United States or other countries. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the United States or other countries could materially adversely affect our results of operations and financial condition.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to our Business

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

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers or key scientific personnel could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We will need to hire additional personnel as we expand our clinical development and commercial activities. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

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

Additionally, we rely on our scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with these advisors or they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

If we are unable to successfully establish and maintain sales or marketing capabilities or enter into agreements with third parties to sell or market FYARRO for advanced malignant PEComa or any additional indications that we may seek approval for, or other product candidates when approved, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

In order to commercialize FYARRO for advanced malignant PEComa or any additional indications that we may seek approval for, or any other product candidate that we may develop in the future, if approved, we must build and maintain marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product(s). There are

risks involved with establishing and maintaining both our own commercial capabilities and entering into arrangements with third parties to perform these services and we may not be successful in accomplishing these required tasks, which may negatively impact the successful commercialization of our product(s), including FYARRO for advanced malignant PEComa, for example.

Establishing and maintaining an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates that we obtain approval to market will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. If the commercial launch of a product candidate for which we recruit a sales team and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on its own. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product sales will suffer, and we may incur significant additional losses.

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

As of September 30, 2022, we had 76 full-time employees, including 46 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, development, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

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

Our future financial performance and our ability to successfully develop and commercialize FYARRO and any other product candidates we may develop in the future, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of our attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

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

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

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

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information or individually identifiable health information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/ or international privacy and security laws.

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

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

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, such as the COVID-19 pandemic, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidate or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations, including at our California headquarters, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our ability to utilize our net operating loss ("NOL") carryforwards and certain other tax attributes to offset future taxable income may be limited.

Our NOL carryforwards may be unavailable to offset future taxable income because of restrictions under United States tax law. Our NOLs generated in tax years beginning before January 1, 2018 are only permitted to be carried forward for 20 taxable years under applicable United States federal tax law, and therefore could expire unused. Under the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs in tax years beginning after December 31, 2020 is limited to 80% of our current year taxable income. NOLs generated in tax years beginning before January 1, 2018 will not be subject to the taxable income limitation and will continue to have a twenty-year carryforward period. It is uncertain if and to what extent various states will conform to the Tax Act. As of December 31, 2021, after consideration of the NOLs that have been estimated to expire unused under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), we had federal NOL carryforwards of approximately $150.9 million, $44.3 million of which will begin to expire in 2030 and the remaining $106.6 million which do not expire. We also have California NOL carryforwards of approximately $44.4 million available as of December 31, 2021, which begin to expire in 2037.

Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent stockholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. We have experienced such ownership changes in the past and we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which are outside our control. To the extent such limitations will cause NOL and research and development credit carryforwards to expire unused, these tax attributes have been removed from our deferred tax asset. Our ability to utilize our NOLs and certain other tax attributes could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

United States federal income tax reform could materially adversely affect our financial condition.

Legislation or other changes in United States and international tax laws could increase our tax liability and adversely affect after-tax profitability. For example, the United States recently enacted the Inflation Reduction Act, which implemented a number of changes, including a 1% excise tax on stock buybacks and an alternative minimum tax on adjusted financial statement income. Such enacted and other proposed changes, as well as regulations and legal decisions interpreting and applying these changes, may have significant impacts on our effective tax rate, cash tax expenses and net deferred tax assets in future periods.

A variety of risks associated with marketing FYARRO or any product candidates that we may develop in the future, if approved, internationally could materially adversely affect our business.

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

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

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

Risks Related to Our Intellectual Property

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

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries for our product and product candidates, proprietary technologies and their uses, and know-how related to our business, as well as our ability to operate without infringing upon the valid and enforceable patents and proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product and product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for us and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product or product candidates could have a material adverse effect on our financial condition and results of operations.

Although we own or license eleven (11) issued patents in the United States, we cannot be certain that the claims in our other United States pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our licensors, will be considered patentable by the United States Patent and

Trademark Office (the "USPTO"), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patent will not be found invalid or unenforceable if challenged.

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

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- if clinical trials encounter delays, the period of time during which we could market our current or future product candidates under patent protection would be reduced;
- patents may be challenged, invalidated, modified, narrowed, revoked, circumvented, found to be unenforceable, found to be not infringed or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that could limit, interfere with or eliminate our ability to make, use and sell our product or potential product candidates or design around any of our owned, co-owned, or licensed patents;
- since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product; or (ii) invent any of the inventions claimed in our patents or patent applications;
- even when laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing products or product candidates.

The patent prosecution process is also expensive, complex, and time-consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we and our licensors will fail to identify patentable aspects of our (or such licensor's) research and development output before it is too late to obtain patent protection. If we are unable to obtain or maintain patent protection with respect to any of our proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products.

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

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. No consistent policy regarding the breadth of

claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. Our pending and future patent applications and those of our licensors may not result in patents being issued that protect our product or product candidates or effectively prevent others from commercializing competitive products or product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and our scope can be reinterpreted after issuance. Even if patent applications we own or in-licenses currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-licenses may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product or product candidates will be protectable or remain protected by valid and enforceable patents.

Our competitors or other third parties may be able to circumvent our patents or the patents of our licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review ("PGR") and *inter partes* review ("IPR"), or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights or put its patent applications at risk of not issuing, allow third parties to commercialize our product or product candidates 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, our patents or the patents of our licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, which challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensors. 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 product or 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. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates. If any of our patents, if and when issued, covering our product candidates are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. We may not prevail in any lawsuits that we or any third-party initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

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

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

- others may be able to develop products that are similar to FYARRO or any future product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

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

Our commercial success depends in part on avoiding infringement or misappropriation of the patents, intellectual property and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our products or products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party United States and foreign issued patents and pending patent applications exist in the fields in which we are developing products or product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product or product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product or product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of our product or any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product or technology. Moreover, because patent applications can take many years to issue, and because patent claims can be revised before issuance, there may be currently pending patent applications that may later result in issued patents that our product or product candidates may infringe or which such third parties claim are infringed by our technologies. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If a patent holder believes one or more of our products or product candidates infringes such holder’s patent rights, the patent holder may sue us even if we have received patent protection. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or

- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this Quarterly Report, others may hold proprietary rights that could prevent FYARRO or our product candidates from being marketed. For example, various patent offices periodically grant mode of action patents and a third party may have or obtain a patent with claims covering modes of action relevant to our product or product candidates. While these mode of action patents may be difficult to enforce, the third party may assert a claim of patent infringement directed at one of our products or product candidates. Any patent-related legal action or any claim relating to intellectual property infringement that is successfully asserted against us claiming damages and seeking to enjoin commercial activities relating to our products or processes could subject us to significant liability for damages, including treble damages and attorney's fees if it was determined that we willfully infringed, and require us to obtain a license to manufacture or market our product or product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our current or future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product or product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent or delay us from developing and commercializing our product or product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of our outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product or product candidates and technology.

In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product or product candidates that we may develop in the future through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product or product candidates that we may develop in the future. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. We may also be unable to license or acquire third-party intellectual property rights on terms that would be favorable to us or allow us to make an appropriate return on our investment or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Competitors and other third parties may infringe, misappropriate, or otherwise violate our patents and other intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the attention of our management and key personnel from our business operations. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our products or product candidates, the defendant could counterclaim that our patent or the patent of our licensors is invalid and/or unenforceable in whole or in part. In

patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution of the patent application.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents or our licensors' patents in such a way that such patents no longer cover our technology or platform, product or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, product or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

The outcome following legal assertions of invalidity and/or unenforceability is unpredictable, and prior art could render our patents or our licensors' patents invalid. There is no assurance that all potentially relevant prior art relating to our patents and patent applications, or the patents and patent applications of our licensors has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

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

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

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

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

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

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product or product candidates to market.

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

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

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

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

Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product or product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and

regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and the patents we might obtain or license in the future.

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

We may also be subject to claims that our former employees or our licensors or other third parties have an ownership interest in our patents or other intellectual property. Confidentiality and intellectual property assignment agreements may not be honored and may not effectively assign intellectual property rights to us. The assignment of intellectual property rights under these agreements may not be automatic upon the creation of the intellectual property 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 it, to determine the ownership of what we regard as our intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product or product candidates that we may develop in the future for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional effective filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product or product candidates that we may develop in the future are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to us.

If we do not obtain patent term extension for our product or product candidates that we may develop in the future, our business may be materially harmed.

In January 2022, we filed an application for patent term extension based on the approval of FYARRO. Depending upon the timing, duration and specifics of FDA regulatory approval of our product candidates that we may develop in the future, one or more of our United States patents or those of our licensors may also be eligible for limited patent term restoration under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request or require. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request or require, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Although we own, co-own, or have licensed at least eleven (11) issued patents in the United States and pending patent applications in the United States and other countries, filing, prosecuting and defending patents on our product or product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. In addition, the statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications and we may not timely file foreign patent applications.

Competitors may use our technologies in jurisdictions where we do not pursue or have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product or product candidates, and our patents, the patents of our licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on our owned and in-licensed patents and/or applications will be due to be paid to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our licensors and any patent rights we may own or license in the future. We have systems in place to remind us to pay these fees, and, in certain instances, we rely on our licensor partners to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and over the lifetime of our owned patents and applications. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, competitors or other third parties might be able to enter the market earlier than would otherwise have been the case and it could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

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

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

We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. However, trade secrets are difficult to protect. For example, we may be required to share our trade secrets with third-party licensees, collaborators, consultants, contractors, or other advisors and we have limited control over the protection of trade secrets used by such third parties. Although we have taken steps to protect our trade secrets and unpatented know-how, including by entering into confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed or that they have been obtained in all circumstances, and it is possible that any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Enforcing a claim that a party illegally obtained, disclosed, used or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. If any of these events occurs or if we otherwise lose protection for our trade secrets or confidential or proprietary information, the value of this information may be greatly reduced, and our competitive position in the marketplace, business, financial condition, results of operations and prospects may be materially adversely affected. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

We have entered into and will enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees, consultants or advisors inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product or product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product or product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including competitors or our potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

We have entered into license agreements with third parties and we may enter into additional license agreements in the future with others to advance our research or allow commercialization of our product or product candidates that we may

develop in the future. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we had licensed may be reduced or eliminated, and our rights to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

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

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

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

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

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

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

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

The patent protection and patent prosecution for our product and product candidates that we may develop in the future may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product or product candidates, there may be times when the filing and prosecution activities for patents are controlled by our licensors or collaboration partners, including those licensed to us under our license agreements. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product or product candidates that we may develop in the future, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize our product or those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. We collaborate with other companies and institutions with respect to research and development matters. Also, we rely on numerous third parties to provide us with materials that we use to develop our technology. If we cannot successfully negotiate sufficient ownership, licensing, and/or commercial rights to any invention that result from our use of any third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's materials, or data developed in a collaborator's study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

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

Our licensed patent applications may have been or may be in the future supported through the use of United States government funding awarded by the National Institute of Health or the FDA Office of Orphan Products Development and the Army Medical Research and Development Command. Although we do not currently own issued patents or pending patent applications that have been generated through the use of United States government funding, we have licensed, or may acquire or license in the future, intellectual property rights that have been generated through the use of United States government funding or grant. Pursuant to the Bayh-Dole Act of 1980, the United States government has certain rights in inventions developed with government funding. These United States government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations ("march-in rights"). The United States government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for United States industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States industry may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property.

Risks Related to Our Reliance on Third Parties

We contract with qualified third parties for the production of FYARRO for commercialization and expect to continue to do so for additional clinical trials. This reliance on third parties, some of which are sole source suppliers, increases the risk that we will not have sufficient quality and quantities of FYARRO to meet demand or otherwise or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have, nor do we plan to acquire, the infrastructure or internal capability to manufacture supplies of FYARRO or any future product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of FYARRO and product candidates for preclinical studies and clinical trials under the guidance of members of our organization. In the case of FYARRO, we rely on a single third-party

manufacturer, Fresenius Kabi, LLC ("Fresenius Kabi"), and currently have no alternative manufacturer in place. On January 13, 2022, we entered into a Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product (the "Fresenius Agreement") with Fresenius Kabi pursuant to which Fresenius Kabi will manufacture FYARRO for intravenous use for us, and we will purchase FYARRO as a finished drug product from Fresenius Kabi, on a purchase-order basis. The Fresenius Agreement will be effective through December 22, 2022 (or such later date as may be agreed between the parties in writing), and we may purchase FYARRO for either clinical or commercial purposes for use in the United States and Canada. The price of FYARRO will be fixed, subject to the ability of Fresenius Kabi to increase pricing under specified circumstances. We also have an obligation to purchase certain minimum quantities of FYARRO and any failure to purchase those minimum quantities will result in an additional payment from us to Fresenius Kabi. We have other supply agreements in place for key raw materials used in the manufacture of FYARRO such as for the drug substance sirolimus and for human albumin, which are key ingredients in the drug product. If we were to engage another third-party manufacturer, we will be required to verify that the new third-party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a bridging study, that any new manufacturing process will produce FYARRO or any other product candidate we may develop in the future, if approved, according to the specifications previously submitted to the FDA or another regulatory authority. If we were to experience an unexpected loss of supply of FYARRO or any other product candidate that we may develop in the future for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations in commercializing FYARRO for advanced malignant PEComa, or be required to restart or repeat, any pending or ongoing clinical trials for FYARRO in other indications or for any other product candidates we may develop in the future, in a timely manner or on budget. Moreover, if we are unable to keep up with demand for FYARRO, our revenue could be impaired, market acceptance for FYARRO could be adversely affected.

We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Further, any delay in identifying and qualifying a manufacturer for commercial production could delay the potential commercialization of FYARRO, and, in the event that we do not have sufficient product to complete our planned clinical trials, it could delay such trials. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture FYARRO or any of our other product candidates that we may develop in the future according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates, are constrained by the recent COVID-19 pandemic or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including manufacturing drug supply pursuant to strictly enforced cGMPs;
- the failure of the third-party contractor to manufacture FYARRO or any of our other product candidates that we may develop in the future according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing both active pharmaceutical ingredients ("API") and finished drug products. To date, we have obtained drug substance and drug product from third-party manufacturers to support preclinical and clinical testing of FYARRO. We are in the process of developing our supply chain for FYARRO, including through the Fresenius Agreement. As we commercialize FYARRO and advance FYARRO for additional indications or any other product candidates we may develop in the future through development, we will consider redundant supply for the API and drug product for FYARRO and each of our product candidates that we may develop in the future to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to pass a pre-approval inspection or secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we do not have control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, many of our CMOs are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our CMOs facilities generally. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of FYARRO or any of our other product candidates that we may develop in the future or if we withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to commercialize FYARRO for advanced malignant PEComa and develop, obtain regulatory approval for or market FYARRO for other indications or any of our other product candidates that we may develop in the future, if approved. Our reliance on CMOs also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on the parties, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of FYARRO or any of our other product candidates or drugs that we may develop in the future and harm our business and results of operations.

In addition, the manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of FYARRO or in our third-party manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any stability or other issues relating to the manufacture of our product candidates may occur in the future. Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause FYARRO or any of our other product candidates that we may develop in the future to perform differently and affect commercialization or the results of planned clinical trials or other future clinical trials. In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at our third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for FYARRO or any of our product candidates that we may develop in the future. Further, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical study costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects. Our current and anticipated future dependence upon others for the manufacture of FYARRO and any of our other product candidates that we may develop in the future may adversely affect our future profit margins and our ability to commercialize FYARRO or any other product candidates that we may develop in the future that receives regulatory approval on a timely and competitive basis.

We are dependent on a single-source supplier for the drug product FYARRO, and the loss of such supplier could harm our business.

We rely on a single-source supplier, Fresenius Kabi for our drug product FYARRO. In January 2022, we entered into the Fresenius Agreement, which is effective through December 22, 2022 (or such later date as may be agreed between the

parties). We also have supply agreements in place for key raw materials used in the manufacture of FYARRO such as for the drug substance sirolimus and for human albumin, which are key ingredients in the drug product. Our suppliers could discontinue the manufacturing or supply of FYARRO at any time. We do not carry a significant inventory of FYARRO or our key raw materials used in the manufacture of FYARRO. Our suppliers may not be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us either entirely or for a particular territory. The loss of any of the foregoing would require significant time and effort to locate and qualify an alternative source of supply. We currently rely on a single company for such manufacturing for FYARRO. Any contractual disputes between us and such manufacturer, the termination of the Fresenius Agreement or loss of manufacturing ability by such manufacturer could similarly require significant time, effort and expense to locate and qualify an alternative source of manufacturing, which could materially harm our business.

In addition, we might not be able to identify and qualify additional or replacement suppliers for the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO timely or at all or without incurring significant additional costs. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. We may also face regulatory delays or be required to seek additional regulatory clearances or approvals if we experience any delay or deficiency in the quality of products obtained from suppliers or if we have to replace our suppliers. In addition, we do not currently have arrangements in place for redundant supply of the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO.

Establishing additional or replacement suppliers for the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO, if required, or any supply interruption from our suppliers, could limit our ability to manufacture our products, result in production delays and increased costs and adversely affect our ability to deliver products to our customers on a timely basis. Our inability to obtain sufficient quantities of the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO also could adversely affect clinical development of FYARRO in other indications. If we are not able to identify alternate sources of supply for the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO, we will not be able to, or may be delayed in our efforts to, successfully commercialize FYARRO or any other product candidate that we may develop in the future or we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for FYARRO in other indications or for any other product candidates that we may develop in the future.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of FYARRO for patients or for clinical trials or any other product candidate that we may develop in the future, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and highly regulated and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and efficacy. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Manufacturing drugs is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or efficacy of the products before and after such changes. If microbial, viral or other contaminations or impurities are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination or impurity, which could delay clinical trials and adversely harm our business. If our third-party manufacturers are unable to produce sufficient quantities of consistent quality for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We entered into a license agreement with Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, now Bristol-Myers Squibb Company (“Celgene”) pursuant to which we have licensed exclusive global rights to intellectual property and know-how related to FYARRO (the “Celgene License”). We are required to use commercially reasonable efforts or diligent efforts to commercialize products based on the licensed rights and to pay certain royalties based off our net sales,

certain sublicense fees and certain other fees. We may not meet these requirements, which could result in a loss or termination of any rights under such agreements. Any termination of these licenses will result in the loss of significant rights and will restrict our ability to commercialize FYARRO.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described above under "Risks Related to Our Intellectual Property." If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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

We do not have the ability to independently conduct all of our preclinical studies and clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct, supervise and monitor our current or planned preclinical studies and clinical trials of FYARRO for additional indications, and we expect to continue to rely upon third parties to conduct additional preclinical studies and clinical trials of FYARRO for additional indications and other product candidates we may develop in the future. We enter into agreements with third parties that have a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the conduct of such third party, the amount or timing of resources that any such third party will devote to our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. The third parties we rely on for these services may also (i) have staffing difficulties, (ii) fail to comply with contractual obligations, (iii) experience regulatory compliance issues, (iv) undergo changes in priorities or become financially distressed, or (v) have relationships with other entities, some of which may be our competitors, which may draw time and resources from our development programs. The third parties with whom we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies and clinical trials being delayed or unsuccessful. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, this would delay our drug development activities.

Our reliance on these third parties for such drug development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and legal, regulatory, and scientific requirements and standards. Moreover, the FDA requires us and our third parties to comply with applicable GLP and GCP standards, regulations for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to assure that the data and reported results are reliable and accurate and for clinical trials that the rights, integrity and confidentiality of trial participants are protected and that they are adequately informed of the potential risks of participating in clinical trials. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies and clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product candidates produced under current cGMP regulations and will require a large number of test patients. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. We are also required to register certain ongoing clinical trials and post the results of certain 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.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not successfully carry out their contractual duties or perform preclinical studies and clinical trials in a satisfactory manner, meet expected deadlines or conduct our preclinical studies and clinical trials in accordance with legal and regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for product candidates that we may develop in the future and will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates, if approved.

We may form or seek strategic alliances or collaborations in the future. Such alliances and collaborations may inhibit future opportunities, or we may not realize the benefits of such collaborations or alliances.

We may form or seek strategic alliances, joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to FYARRO or any future product candidates that we may develop. We are at risk that any such future collaborations may not be successful. Factors that may affect the success of our collaborations include the following:

- our collaboration partners may incur financial and cash flow difficulties that force them to limit or reduce their efforts under their collaboration agreement with us;
- our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others;
- our collaboration partners may terminate their collaboration with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities; and
- our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

In addition, any future collaboration agreements we may enter into, are generally subject to termination by the counterparty on short notice upon the occurrence of certain circumstances without cause subject to a specified notice period. Accordingly, even if we believe that the development of product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, we may not receive additional milestones or royalties under those collaborations. In addition, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaboration or other arrangements that we establish may not be favorable to us. For example, in December 2020, we granted to EOC exclusive rights to develop and commercialize FYARRO in the EOC Licensed Territory. Under the EOC License Agreement, we received an upfront payment and were eligible to receive regulatory and sales-based milestone payments upon the occurrence of certain milestone events totaling $257 million, as well as tiered royalties based on annual net sales of FYARRO. In addition, EOC was responsible for development, regulatory submissions, and commercialization in China, Hong Kong, Macau and Taiwan (collectively, the “EOC Territory”). On June 27, 2022, EOC elected to terminate the EOC License Agreement, effective immediately, due to alleged material breaches by us. We disagree with, and continue to dispute, EOC’s allegations of material breach and do not believe that EOC had a right to terminate the EOC License Agreement for material breach, and accordingly believe that the termination of the EOC License Agreement is a termination for convenience. EOC had the right to terminate the agreement for convenience upon 120 days advance written notice. We waived such notice period in connection with EOC's termination notice and, as a result, the EOC License Agreement was terminated effective June 27, 2022. Under the EOC License Agreement, we relied on EOC for a substantial portion of the financial resources and for the development, regulatory, and commercialization activities for FYARRO in the EOC Territory. In addition, EOC's termination of the EOC License Agreement prior to completing development or commercialization of the FYARRO under the collaboration adversely impacts the potential approval and our revenue from the licensed product in the EOC Territory and we will not receive future revenues from the collaboration. It may be necessary for us to assume the responsibility at our own expense for the development of FYARRO in the EOC Territory or find another partner for the territory. In that event, we would likely need to seek additional funding and our potential to generate future revenues from FYARRO could be significantly reduced and our business could be materially and adversely harmed.

Future efforts for additional alliances or collaborations may also require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Furthermore, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction

If we cannot maintain successful collaborations, our business, financial condition, and operating results may be adversely affected.

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

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

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

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

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

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

We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

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

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our 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.

We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If we enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than us;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of FYARRO or any other product candidate that we may develop in the future, if approved, relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products that results from us collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements. For example, on June 27, 2022, EOC elected to terminate the EOC License Agreement, effective immediately, due to alleged material breaches by us. We disagree with, and continue to dispute, EOC's allegations of material breach and do not believe that EOC had a right to terminate the EOC License Agreement for material breach, and accordingly believe that the termination of the EOC License Agreement is a termination for convenience. EOC had the right to terminate the agreement for convenience upon 120 days advance

written notice. We waived such notice period in connection with EOC's termination notice and, as a result, the EOC License Agreement was terminated effective June 27, 2022. Under the EOC License Agreement, we relied on EOC for a substantial portion of the financial resources and for the development, regulatory, and commercialization activities for FYARRO in the EOC Territory. In addition, EOC's termination of the EOC License Agreement prior to completing development or commercialization of the FYARRO under the collaboration adversely impacts the potential approval and our revenue from the licensed product in the EOC Territory and we will not receive future revenues from the collaboration. It may be necessary for us to assume the responsibility at our own expense for the development of FYARRO in the EOC Territory or find another partner for the territory. In that event, we would likely need to seek additional funding and our potential to generate future revenues from FYARRO could be significantly reduced and our business could be materially and adversely harmed.

General Risks

Litigation and legal proceedings, including the EOC dispute, may substantially increase our costs and harm our business.

As described in Note 15 (Commitments and contingencies) to the condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q, we have been, are, and may in the future become, party to lawsuits and legal proceedings including, without limitation, actions and proceedings in the ordinary course of business relating to our collaboration partners, directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products, which will cause us to incur legal fees and other costs related thereto, including potential expenses for the reimbursement of legal fees of officers and directors under indemnification obligations. On June 27, 2022, EOC filed a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against us. In the Request for Arbitration, EOC claims that we breached certain provisions of the EOC License Agreement, including failing to provide certain manufacturing and clinical development information to EOC. As a result, EOC is seeking monetary damages. The arbitration process is ongoing.

The expense of defending against such litigation and legal proceedings may be significant and there can be no assurance that we will be successful in any defense. Further, the amount of time that may be required to resolve such lawsuits or legal proceedings is unpredictable, and these actions may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Litigation and legal proceedings are subject to inherent uncertainties, and an adverse result in such matters that may arise from time to time could have a material adverse effect on our business, results of operations, and financial condition.

Our stock price is volatile.

The market price of our common stock could be subject to significant fluctuations. From the completion of the Merger through September 30, 2022, the market price for our common stock ranged from a low of $11.00 to a high of $32.99. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for FYARRO in other indications or for any other product candidates that we may develop in the future, and delays or failures to obtain such approvals;
- the failure of FYARRO or any product candidates that we may develop in the future, if approved for marketing and commercialization, to achieve commercial success;
- any inability to obtain adequate supply of FYARRO or any of our product candidates that we may develop in the future or the inability to do so at acceptable prices;
- the entry into, or termination of, key agreements, including key licensing, supply or collaboration agreements;
- adverse regulatory authority decisions;
- the initiation of material developments in, or conclusion of, disputes or litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- changes in laws or regulations applicable to FYARRO or any of our product candidates that we may develop in the future;

- the results of current, and any future, nonclinical or clinical trials of FYARRO or any of our product candidates that we may develop in the future;
- announcements by commercial partners or competitors of new commercial products, clinical progress (or the lack thereof), significant contracts, commercial relationships, or capital commitments;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine;
- adverse publicity relating to our markets, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies competing with our products and potential products;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the loss of key employees;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general and industry-specific economic conditions potentially affecting our research and development expenditures;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in the structure of health care payment systems;
- adverse regulatory decisions;
- trading volume of our common stock; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies or the biotechnology sector. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Regardless of the merits or the ultimate results of such litigation, if instituted, such litigation could result in substantial costs and diversion of management's attention and resources, which could significantly harm our profitability and reputation.

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business and stock price.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, and therefore will be able to take advantage of certain exemptions from various reporting requirements that are applicable to other companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our disclosure controls and procedures quarterly and the effectiveness of our internal control over financial reporting at the end of each fiscal year. We rely heavily on direct management oversight of transactions, along with the use of legal and outsourced accounting professionals. As we grow, we plan to hire additional personnel and engage external temporary resources and may implement, document, and modify policies and procedures to maintain effective internal controls. However, we may identify deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are applicable to us as a public company. If we fail to staff our accounting, finance and information technology functions adequately or maintain internal control over financial reporting adequate to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed and our stock price may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our common stock.

Financial reporting obligations of being a public company in the United States are expensive and time- consuming, and our management will be required to devote substantial time to compliance matters.

Following the recently completed Merger, we have incurred and expect to continue to incur significant additional legal, accounting and other expenses as a publicly traded company that we did not incur as a privately held company, including costs associated with public company reporting requirements. The obligations of being a public company in the United States require significant expenditures and place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") and the Nasdaq listing requirements. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. For example, some of our management have not previously managed and operated a public company. Thus, our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems. In addition, these rules and regulations may also make it difficult and expensive for us to obtain and maintain director's and officer's liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence in and could cause our business or stock price to suffer.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of new and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

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

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant portion of our outstanding voting stock.

These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact the elections of directors, amendments to our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholder and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

Our results of operations could be adversely affected by war, terrorism, geopolitical uncertainties, other business interruptions, and by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. In the event of prolonged business interruptions due to geopolitical events, we could incur significant losses, require substantial recovery time and experience significant expenditures in order to resume our business or clinical operations. We have no operations in Russia, Belarus or Ukraine, but we do not and cannot know if the current uncertainties in these geopolitical areas, which are unfolding in real-time, may escalate and result in broad economic and security conditions or rationing of medical supplies, which could limit our ability to conduct clinical trials outside the United States or result in material implications for our business. In addition, our insurance policies typically contain a war exclusion of some description and we do not know how our insurers are likely to respond in the event of a loss alleged to have been caused by geopolitical uncertainties. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In addition, our operations and performance may be affected by political or civil unrest or military action, including the current conflict between Russia and Ukraine, terrorist activity, unstable governments and legal systems. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. Our ability to conduct clinical trials in regions experiencing political or civil unrest could negatively affect clinical trial enrollment or the timely completion of a clinical trial. We believe the aforementioned economic conditions could lead to reduced demand for our drug products, which could have a material adverse effect on our revenues, business and results of operations.

We are a smaller reporting company. We cannot be certain whether the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors or otherwise limit our ability to raise additional funds.

We are a "smaller reporting company" under applicable securities regulations. A smaller reporting company is a company that, as of the last business day of its most recently completed second fiscal quarter, has (i) an aggregate market value of the company's voting stock held by non-affiliates, or public float, of less than $250 million or (ii) less than $100 million in revenue and less than $700 million in public float. SEC rules provide that companies with a public float of less than $75 million may only sell shares under a Form S-3 shelf registration statement, during any 12-month period, in an amount less than or equal to one-third of the public float. If we do not meet this public float requirement, any offering by us under a Form S-3 will be limited to raising an aggregate of one-third of our public float in any 12-month period. In addition, a smaller reporting company is able to provide simplified executive compensation disclosures in its filings and has certain other reduced disclosure obligations in our SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain, if any, for the foreseeable future.

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

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

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We will be highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts our stockholders to replace or remove our management.

Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us in certain circumstances. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees or our stockholders to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provisions of the DGCL, or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, our amended and restated certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. The amended and restated bylaws provide that the federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity

purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Employees may also unintentionally or willfully disclose our proprietary and/or confidential information to competitors. 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 restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending our self or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

There have been no unregistered sales of securities other than previously disclosed by us in our Current Report on Form 8-K, as filed with the SEC on September 22, 2022.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 27, 2021).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on August 27, 2021).
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 22, 2022).
10.1	Form of Securities Purchase Agreement, dated September 22, 2022, by and among the Company and the Purchasers (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 22, 2022).
10.2	Form of Registration Rights Agreement, dated September 22, 2022, by and among the Company and the Purchasers (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 22, 2022).
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 Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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 (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 and Exhibit 32.2 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 them by reference.

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.

AADI BIOSCIENCE, INC.

Date: November 9, 2022

By: */s/ Scott Giacobello*

Scott Giacobello

Chief Financial Officer

(Principal Financial Officer and Duly Authorized 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, Neil Desai, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aadi Bioscience, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2022

By: /s/ Neil Desai, Ph.D.

Neil Desai, Ph.D.
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, Scott Giacobello, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aadi Bioscience, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2022

By: /s/ Scott Giacobello

Scott Giacobello
Chief Financial Officer
(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 the Quarterly Report of Aadi Bioscience, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neil Desai, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: November 9, 2022

By: /s/ Neil Desai, Ph.D.

Neil Desai, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 the Quarterly Report of Aadi Bioscience, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott Giacobello, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: November 9, 2022

By: /s/ Scott Giacobello

Scott Giacobello
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)