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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38560

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 ☒ No ☐

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

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

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

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

As of May 3, 2024, the registrant had 24,554,205 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AADI BIOSCIENCE, INC.

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 53,780	$ 62,888
Short-term investments	34,491	45,957
Accounts receivable, net	4,933	5,488
Inventory	5,936	6,427
Prepaid expenses and other current assets	3,433	3,826
Total current assets	102,573	124,586
Property and equipment, net	5,686	4,802
Operating lease right-of-use assets	1,077	1,169
Other assets	1,737	1,866
Total assets	$ 111,073	$ 132,423
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,095	$ 5,898
Accrued liabilities	10,598	14,306
Operating lease liabilities, current portion	425	434
Due to licensor payable (Note 7)	5,757	5,757
Total current liabilities	19,875	26,395
Operating lease liabilities, net of current portion	738	833
Total liabilities	20,613	27,228
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized; 24,554,205 shares issued and outstanding as of March 31, 2024 and December 31, 2023	2	2
Additional paid-in capital	377,718	374,129
Accumulated other comprehensive (loss) income	(8)	27
Accumulated deficit	(287,252)	(268,963)
Total stockholders' equity	90,460	105,195
Total liabilities and stockholders' equity	$ 111,073	$ 132,423

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

AADI BIOSCIENCE, INC.

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

	Three Months Ended March 31,	
	2024	2023
Revenue		
Product sales, net	$ 5,353	$ 5,867
Total revenue	5,353	5,867
Operating expenses		
Selling, general and administrative	10,620	11,207
Research and development	13,593	10,956
Cost of goods sold	652	529
Total operating expenses	24,865	22,692
Loss from operations	(19,512)	(16,825)
Other income (expense)		
Foreign exchange loss	(1)	—
Interest income	1,282	1,660
Interest expense	(58)	(58)
Total other income (expense), net	1,223	1,602
Net loss	$ (18,289)	$ (15,223)
Other comprehensive (loss) income:		
Unrealized (loss) income on available-for-sale debt securities	(35)	83
Comprehensive loss	(18,324)	(15,140)
Net loss per share, basic and diluted	$ (0.68)	$ (0.57)
Weighted average number of common shares outstanding, basic and diluted	26,980,698	26,862,646

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands, including share amounts)
(Unaudited)

	For the Three Months Ended March 31, 2024					
	Stockholders' Equity					
	Common Stock					
	Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balance at December 31, 2023	24,554	$ 2	$ 374,129	$ 27	$ (268,963)	$ 105,195
Share-based compensation expense	—	—	3,589	—	—	3,589
Unrealized loss on investments, net of tax	—	—	—	(35)	—	(35)
Net loss	—	—	—	—	(18,289)	(18,289)
Balance at March 31, 2024	24,554	$ 2	$ 377,718	$ (8)	$ (287,252)	$ 90,460

	For the Three Months Ended March 31, 2023					
	Stockholders' Equity					
	Common Stock					
	Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balance at December 31, 2022	24,435	$ 2	$ 361,689	$ (115)	$ (203,198)	$ 158,378
Share-based compensation expense	—	—	2,740	—	—	2,740
Issuance of common stock upon exercise of stock options	2	—	8	—	—	8
Unrealized gain on investments, net of tax	—	—	—	83	—	83
Net loss	—	—	—	—	(15,223)	(15,223)
Balance at March 31, 2023	24,437	$ 2	$ 364,437	(32)	$ (218,421)	$ 145,986

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (18,289)	$ (15,223)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	3,589	2,740
Discount amortization on short-term investments	(422)	(1,200)
Non-cash interest expense	58	58
Non-cash lease expense	115	116
Depreciation and amortization expense	50	38
Changes in operating assets and liabilities:		
Accounts receivable	555	(3,703)
Inventory	490	(1,942)
Prepaid expenses and other current assets	953	(642)
Other non-current assets	138	116
Operating lease liabilities	(126)	(124)
Accounts payable and accrued liabilities	(6,764)	(1,544)
Net cash used in operating activities	(19,653)	(21,310)
Cash flows from investing activities:		
Purchases of property and equipment	(739)	(1,369)
Purchase of short-term investments	(7,646)	(23,052)
Maturity of short-term investments	18,940	40,750
Net cash provided by investing activities	10,555	16,329
Cash flows from financing activities:		
Issuance of common stock upon exercise of stock options	—	8
Deferred offering costs paid for financing	(10)	—
Net cash (used in) provided by financing activities	(10)	8
Net decrease in cash, cash equivalents and restricted cash	(9,108)	(4,973)
Cash, cash equivalents and restricted cash at beginning of period	62,952	39,083
Cash, cash equivalents and restricted cash, end of period	$ 53,844	$ 34,110
Supplemental disclosure of cash flow information:		
Interest paid during the period	$ 58	$ 58
Supplemental disclosure of non-cash activities:		
Accrued property and equipment	$ 540	$ 387

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 cancers with alterations in the mTOR pathway, a key regulator of cell growth and cancer progression. Aadi's lead drug product, FYARRO®, combines two established technologies — nanoparticle albumin-bound (*nab*) technology and the anti-cancer agent, sirolimus. *Nab*-sirolimus is a potent inhibitor of the mTOR biological pathway with demonstrated anti-cancer activity in Aadi's lead indication, advanced unresectable or metastatic malignant perivascular epithelioid cell tumor ("PEComa"), a rare cancer. 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 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, which is a wholly owned subsidiary of Bristol-Myers Squibb Company ("BMS").

The Company's historical operations have consisted principally of sales of FYARRO after receiving FDA approval, 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.

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 $287.3 million as of March 31, 2024 and a net loss of $18.3 million and $15.2 million for the three months ended March 31, 2024 and 2023, 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 $88.3 million at March 31, 2024. 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. If the Company is unable to achieve and maintain profitability, it will need additional financing to support its continuing operations and pursue its strategic objectives. Additional financing may be achieved through a combination of equity offerings, and debt financings. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all.

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 price of up to $75.0 million through Cowen as its sales agent for an at-the-marketing-offering. Any sales under the Sales Agreement may result in dilution to existing shareholders. As of March 31, 2024, no shares of common stock had been sold under this Sales Agreement.

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 accounting principles generally accepted in the United States ("GAAP") and U.S. Securities and Exchange Commission ("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 prior year amounts have been reclassified to conform to the current year presentation.

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, 2023, which are included in the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2024.

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 condensed consolidated 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 gross-to-net accruals, share-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 available-for-sale marketable debt securities. 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. While the Company has not experienced any losses in such deposits, the recent failure of Silicon Valley Bank, at which the Company holds cash and cash equivalents in multiple accounts, exposed the Company to credit risk prior to the resolution by the Federal Deposit Insurance Corporation in a manner that fully protected all depositors. The Company has not experienced any losses on deposits since inception.

The Company's accounts receivable is derived from customers located in the United States. The Company performs ongoing credit evaluations of its customers and maintains allowances for potential credit losses on customers' accounts when deemed necessary. The Company does not typically require collateral from its customers. Credit losses historically have not been material. The Company continuously monitors customer payments and maintains an allowance for credit losses based on its assessment of various factors including historical experience, age of the receivable balances, and other current economic conditions or other factors that may affect customers' ability to pay.

Customer Concentration

For the three months ended March 31, 2024, two customers represented 48% and 52% of the Company's revenue. For the three months ended March 31, 2023, two customers represented 51% and 48% of the Company's revenue.

Additionally, two customers accounted for 51% and 49% of net accounts receivable as of March 31, 2024.

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. 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 6, and is included in other assets on the condensed consolidated balance sheets.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets (in thousands):

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 53,780	$ 62,888
Restricted cash, non-current	64	64
Total cash, cash equivalents and restricted cash	$ 53,844	$ 62,952

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 equivalents, accounts receivable, accounts payable, accrued liabilities, and due to licensor payable are reasonable estimates of their fair value because of the short maturity of these items.

Short-Term Investments

The Company invests in various types of securities, including United States government treasury bills, commercial paper, corporate debt securities, and government agency bonds. The Company classifies its investments as available-for-sale and records them at fair value based upon market prices at period end. Unrealized gains and losses that are deemed temporary in nature are recorded in accumulated other comprehensive loss as a separate component of stockholders' equity. Dividend and interest income are recognized when earned. The Company recognizes purchase premiums and discounts as interest income using the interest method over the terms of the securities. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold. 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.

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the decline in fair value below amortized cost is a result of credit losses or other factors, whether the Company expects to recover the amortized cost of the security, the Company's intent to sell and if it is more likely than not that the Company will be required to sell the securities before the recovery of amortized cost. The Company records changes in allowance for expected credit loss in other income (expense). There has been no allowance for expected credit losses recorded during any of the periods presented. See Note 4 for further information.

Accounts Receivable, Net

Accounts receivable are recorded net of customer allowances for chargebacks and allowance for credit losses. Allowance for chargebacks is based on contractual terms. The Company estimates the allowance for credit losses based on existing contractual payment terms, actual payment patterns of its customers, individual customer circumstances and credit loss. Receivables are recorded to an allowance for credit loss when it is probable that amounts will not be collected based on

terms of the customer contracts. Accounts receivable are net of $0.1 million and $0.2 million, of customer allowances for chargebacks as of March 31, 2024 and December 31, 2023, respectively. There were no allowances for credit losses and no receivables were written off for the periods ended March 31, 2024 and December 31, 2023.

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.

Details of inventory are presented as follows (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	$ 3,606	$ 4,640
Work in process	1,660	1,366
Finished goods	670	421
Total	$ 5,936	$ 6,427

Property and Equipment, Net

Property and equipment, consisting of computers and software, construction in process, furniture and fixtures, lab equipment, 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.

Details of property and equipment are presented as follows (in thousands):

	March 31, 2024	December 31, 2023
Computers and Software	$ 471	$ 464
Construction in process	5,312	4,389
Furniture and fixtures	65	65
Lab equipment	25	25
Leasehold improvements	133	129
Total	$ 6,006	$ 5,072
Accumulated depreciation	(320)	(270)
Property and equipment, net	$ 5,686	$ 4,802

Construction in process mainly consists of lab, production, and testing equipment. Depreciation expense on property, plant, and equipment amounted to $50,000 and $38,000 for the three months ended March 31, 2024 and 2023, respectively.

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 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 condensed consolidated 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 March 31, 2024 and December 31, 2023.

Revenue Recognition and Related Allowances

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 Customers ("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 ("SDs") 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 requirements. 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 months ended March 31, 2024, and 2023, was $1.1 million and $1.0 million, respectively.

The following table sets forth the changes in the accrued revenue allowances (in thousands):

	As of March 31,	
	2024	**2023**
Balance at beginning of period	$1,065	$1,434
Provision for current period sales	1,084	1,035
Payments	(1,292)	(553)
Balance at end of period	$857	$1,916

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, share-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 condensed consolidated balance sheets and within research and development expenses in the condensed consolidated 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 share-based payments to employees, including grants of employee stock options and restricted stock units in the 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. Compensation expense for awards to employees is calculated on a straight-line basis by recognizing the fair value over the associated service period of the award, which is generally the vesting term. Options granted during the year have a maximum contractual term of ten years.

Employee Stock Purchase Plan

Stock-based compensation expense for employee stock purchases under the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP") is recorded at the estimated fair value of the purchase as of the plan enrollment date and is recognized as an expense on a straight-line basis over the applicable six-month 2021 ESPP offering period.

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

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 and diluted weighted average shares of common stock outstanding for the three months ended March 31, 2024, includes the weighted average effect of 2,426,493 Pre-Funded Warrants, which were issued in September 2022, for the purchase of shares of common stock, for which the remaining unfunded exercise price is $0.0001 per share. See Note 8 for more information on the Pre-Funded Warrants.

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 outstanding stock options, restricted stock units, and warrants have been excluded from the computation of diluted net loss per share as they would be anti-dilutive.

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

	Three Months Ended March 31,	
	2024	2023
Options to purchase common stock	5,372,887	3,846,365
Restricted Stock Units to purchase common stock	341,258	—
Warrants to purchase common stock	29,167	29,167

Recent Accounting Pronouncements

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. ASU 2020-06 is not applicable to the Company's consolidated financial position and results of operations.

In December 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures. The new standard requires a company to disclose incremental segment information on an annual and interim basis, including significant segment expenses and measures of profit or loss that are regularly provided to the chief operating decision maker. The standard is effective for the Company beginning in fiscal year 2024 and interim periods within fiscal year 2025, with early adoption permitted. The standard is not expected to have a material impact to the Company's condensed consolidated financial statements.

In December 2023, the FASB also issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The standard is effective for the Company beginning in fiscal year 2025, with early adoption permitted. The Company does not expect to early adopt the new standard. The new standard is expected to be applied prospectively, but retrospective application is permitted. The Company is currently evaluating the impact of ASU 2023-09 on the consolidated financial statements and related disclosures.

3. Fair Value Measurement

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 (in thousands):

	Fair Value Measurements as of March 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	$ 51,924	$ —	$ —	$ 51,924
U.S. government treasury bills	15,527	—	—	15,527
Commercial paper	—	7,469	—	7,469
Corporate bonds	—	11,495	—	11,495
Total financial assets	$ 67,451	$ 18,964	$ —	$ 86,415

	Fair Value Measurements as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	$ 61,034	$ —	$ —	$ 61,034
U.S. government treasury bills	19,458	—	—	19,458
Commercial paper	—	8,717	—	8,717
Corporate bonds (2)	—	13,447	—	13,447
Government agency	—	5,482	—	5,482
Total financial assets	$ 80,492	$ 27,646	$ —	$ 108,138

(1) Included in cash and cash equivalents in the accompanying condensed consolidated balance sheets.

(2) Includes $1.1 million of corporate bonds in cash and cash equivalent in the accompanying consolidated balance sheet.

As of March 31, 2024, net unrealized loss on investments was $8,000. All marketable securities had a contractual maturity of less than one year as of March 31, 2024.

4. Short-Term Investments and Cash Equivalents

The following table summarizes the Company's short-term investments (in thousands):

		As of March 31, 2024			
	Maturity (In Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds		$ 51,924	$ —	$ —	$ 51,924
U.S. government treasury bills	Less than 1	15,534	1	(8)	15,527
Commercial paper	Less than 1	7,470	2	(3)	7,469
Corporate bonds	Less than 1	11,495	3	(3)	11,495
Total		$ 86,423	$ 6	$ (14)	$ 86,415

		As of December 31, 2023			
	Maturity (In Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds		$ 61,034	$ —	$ —	$ 61,034
U.S. government treasury bills	Less than 1	19,441	17	—	19,458
Commercial paper	Less than 1	8,712	6	(1)	8,717
Corporate bonds	Less than 1	13,438	10	(1)	13,447
Government agency	Less than 1	5,486	—	(4)	5,482
Total		$ 108,111	$ 33	$ (6)	$ 108,138

5. Accrued Liabilities

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

	March 31, 2024	December 31, 2023
Accrued professional fees	$ 1,564	$ 2,504
Accrued salaries and payroll	1,724	1,590
Accrued bonus	1,336	3,081
Accrued clinical	1,402	1,416
Accrued contract manufacturing	3,279	4,315
Accrued other - sales related	738	772
Accrued other	555	628
Total accrued liabilities	$ 10,598	$ 14,306

6. Operating Leases

In April 2019, the Company entered into a twenty-eight month facility lease agreement for 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. 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 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 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 leases (in thousands):

	March 31, 2024	December 31, 2023
Assets:		
Operating lease right-of-use assets	$ 1,077	$ 1,169
Liabilities:		
Operating lease liabilities, current	$ 425	$ 434
Operating lease liabilities, non-current	738	833
Total operating lease liabilities	$ 1,163	$ 1,267

Rent expense for the three months ended March 31, 2024 and 2023 is presented on the following table (in thousands):

	Three Months Ended March 31,	
	2024	2023
Operating lease rent expense	$ 115	$ 116

Cash paid for leases and included in operating cash flows for the three months ended March 31, 2024 and 2023 is presented on the following table (in thousands):

	Three Months Ended March 31,	
	2024	2023
Cash paid included in operating cash flows	$ 126	$ 124

The future minimum lease payments required under the operating leases as of March 31, 2024, are summarized below (in thousands):

Future Minimum Lease Payments:	
2024	$ 386
2025	320
2026	231
2027	280
2028	109
Thereafter	—
Total minimum lease payments	$ 1,326
Less: amount representing interest	(163)
Present value of operating lease liabilities	$ 1,163
Less: operating lease liabilities, current	(425)
Operating lease liabilities, non-current	$ 738
Remaining lease term (in years)	3.60
Incremental borrowing rate	7.55 %

The Company includes the option to renew the lease as part of the right of use lease asset and liability when it is reasonably certain the Company will exercise the option. In general, the Company is not reasonably certain to exercise such options.

7. License Agreements

Bristol-Myers Squibb Company License Agreement

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

The BMS 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 pursuant to the terms of the BMS License Agreement, including providing advance notice as specified in the agreement. Under the terms of the BMS License Agreement, BMS agreed to supply the Company with licensed products of FYARRO necessary for clinical or non-clinical development.

Under the terms of the BMS License Agreement, BMS is entitled to receive royalties on net sales from licensed products under the agreement and any sublicense fees. During the three months ended March 31, 2024 and 2023, royalties on net product sales were $0.4 million. No payments related to sublicense fees were paid during the three months ended March 31, 2024 or 2023.

On August 30, 2021, the Company and BMS entered into Amendment No. 1 (the "Amendment") to the BMS License Agreement related to certain intellectual property rights of BMS pertaining to the compound known as FYARRO. Under the terms of the Amendment, the Company paid BMS $5.8 million representing 50% of the previously outstanding payment obligation under the terms of the BMS License Agreement, following the effective time of the 2021 private investment in public equity financing (the "2021 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 of the 2021 PIPE Financing, or August 26, 2024 plus any accrued and unpaid interest due thereon (the "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 BMS based on net sales of products subject to the BMS License Agreement.

EOC 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 BMS License Agreement, the Company is required to pay 20% of all sublicense fees to BMS.

The Company assessed the EOC License Agreement and concluded that EOC was a customer and identified the license of FYARRO 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 BMS License Agreement, 20% of the $1.0 million payment, or $0.2 million was accrued at December 21, 2021, and paid in January 2022.

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.

8. Stockholders' Equity

Preferred Stock

As of March 31, 2024 and December 31, 2023, 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.

Common Stock and Pre-Funded Warrants

As of March 31, 2024 and December 31, 2023, 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 March 31, 2024 and December 31, 2023, the shares of common stock outstanding were 24,554,205.

In March 2022, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company LLC ("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. The Company will pay Cowen 3.0% of the aggregate gross proceeds from each sale of shares of common stock under the Sales Agreement. As of March 31, 2024, no shares of common stock had been sold pursuant to the Sales Agreement.

On September 22, 2022, the Company entered into a securities purchase agreement (the "Purchase Agreement") for a private investment in public equity financing (the "2022 PIPE Financing") with certain investors (the "2022 PIPE Investors") for the sale by the Company of (i) 3,373,526 shares of the Company's common stock for a price of $12.50 per share and (ii) pre-funded warrants to purchase an aggregate of 2,426,493 shares of the Company's common stock (the "Pre-Funded Warrants") 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 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 2022 PIPE Financing closed on September 26, 2022. Aggregate net proceeds, after deducting certain expenses incurred of $0.3 million related to the issuance of the shares were $72.2 million.

On September 26, 2022, the Company and the 2022 PIPE Investors entered into a Registration Rights Agreement (the "2022 PIPE 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. As of March 31, 2024, all Pre-Funded Warrants are still outstanding.

Dividends

The holders of common stock are entitled to receive cash dividends, if and when declared by the board of directors of the Company (the "board of directors"). Since the Company's inception, no cash 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 at all meetings of stockholders for each share of common stock held by such stockholders as of the record date.

9. Share-Based Compensation

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.

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 the adoption of the 2021 Plan (as defined below).

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 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 982,168 shares of common stock were added to the 2021 Plan on January 1, 2024 and 977,400 shares of common stock were added to the 2021 Plan on January 1, 2023.

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).

2023 Inducement Equity Incentive Plan

On September 27, 2023 the Company adopted the 2023 Inducement Equity Incentive Plan (the "Inducement Plan"), pursuant to which the Company may from time to time make equity grants to new employees as a material inducement to their employment. The Company reserved 600,000 shares of common stock for issuance under the Inducement Plan. The

only persons eligible to receive awards under the Inducement Plan are individuals who are new employees and satisfy the standards for inducement grants under applicable Nasdaq listing rules.

As of March 31, 2024, 256,456, 37,921, 4,929,768, and 490,000 shares were outstanding under the 2014 Private Aadi Plan, 2017 Plan , 2021 Plan, and 2023 Inducement Plan, respectively. As of March 31, 2024, no shares were outstanding under the 2011 Plan.

The following table summarizes the stock option activity during the three months ended March 31, 2024:

	Stock Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, January 1, 2024	4,579,659	$ 14.11	8.37	$ 25
Granted	1,088,059	1.92		
Exercised	—	—		
Expired/cancelled	(294,831)	12.52		
Outstanding as of March 31, 2024	5,372,887	$ 11.68	8.56	$ 504
Options exercisable as of March 31, 2024	2,285,885	$ 13.92	8.02	$ 244
Vested and expected to vest as of March 31, 2024	5,372,887	$ 11.68	8.56	$ 504

As of March 31, 2024, there was $21.3 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 2.32 years.

The total intrinsic value of the options exercised during the three months ended March 31, 2024, and 2023, was $0 and $16,000, respectively

As of March 31, 2024, and December 31, 2023, 647,974 and 657,734 shares were reserved for issuance under the 2021 Plan, respectively. As of March 31, 2024 and December 31, 2023, 110,000 shares were reserved for issuance under the 2023 Inducement Plan.

Restricted Stock Units

Restricted stock consists of restricted stock unit awards (RSUs) which have been granted to employees. The value of an RSU award is based on the Company's stock price on the date of grant. Employee grants vest over four years. Forfeitures

of RSUs are recognized as they occur. The shares underlying the RSU awards are not issued until the RSUs vest. Upon vesting, each RSU converts into one share of the Company's common stock.

Activity with respect to the Company's restricted stock units during the three months ended March 31, 2024 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Nonvested shares at January 1, 2024	32,558	$ 4.30
Granted	308,700	1.92
Vested/Issued	—	—
Forfeited	—	—
Nonvested shares at current period end	341,258	$ 2.15

As of March 31, 2024, there was $0.7 million of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 3.55 years.

Compensation Expense Summary

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

	Three Months Ended March 31,	
	2024	2023
Selling, general and administrative	$ 2,342	$ 1,640
Research and development	1,247	1,100
Total	$ 3,589	$ 2,740

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for share-based option 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. Forfeitures are recognized and accounted for as they occur.

The calculation was based on the following assumptions:

	Three Months Ended March 31,	
	2024	2023
Weighted average grant date fair value (per share)	$1.43	$8.57
Risk-free interest rate	4.13% - 4.14%	3.42% - 4.17%
Expected volatility	89.22% - 91.46%	89.94% - 95.72%
Expected term (in years)	5.0 - 6.1	5.8 - 6.1
Expected dividend yield	—	—

The Company determines the assumptions used in the option pricing model in the following manner:

Risk-Free Interest Rate – For the determination of the risk-free interest rates, the Company utilizes the U.S. Treasury yield curve for instruments in effect at the time of measurement with a term commensurate with the expected term assumption.

Expected Volatility – The Company based its estimate of expected volatility on a weighted average using the Company's limited historical stock price volatility data, supplemented with the estimated and expected volatilities of a guideline group of publicly traded companies. For these analyses, the Company selected companies with comparable characteristics including enterprise value, risk profiles, and with historical share price information sufficient to meet the expected life of the share-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its share-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected Dividend – The expected dividend yield is assumed to be zero because the Company has never paid dividends and does not have current plans to pay any dividends on its common stock.

Expected Term – The Company estimates the expected term of its stock options granted to employees and non-employee directors using the simplified method, whereby, the expected term equals the average of the vesting term and the original

contractual term of the option. The Company utilizes this method since it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Merger Warrants to Purchase Common Stock

The Company had warrants outstanding for the purchase of 29,167 shares of the Company's common stock at both March 31, 2024, and December 31, 2023. These 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 a ratio of 15:1 effected on August 26, 2021 immediately prior to the closing of the Merger, (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 warrants were fully vested as of the date of the Merger and expire on October 24, 2024. No warrants were exercised during the three months ended March 31, 2024. 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 warrants meet the criteria to be classified within stockholders' equity.

10. 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 ESPP which permits participants to contribute up to 15% of their eligible compensation during defined rolling six-month offering periods to purchase the Company's common stock. The purchase price of the shares will be 85% of the lower of the fair market value of the Company's common stock on the first day of trading of the offering period or on the applicable purchase date. Upon approval of the 2021 ESPP by the stockholders, Aerpio's Amended and Restated 2017 Employee Stock Purchase Plan terminated. An aggregate of 519,563 shares of common stock was initially reserved for issuance under the 2021 ESPP. The number of shares of common stock available for issuance under the 2021 ESPP is 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, (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. On January 1, 2024, 245,542 shares of common stock were added to the 2021 ESPP. 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.

The Company uses the Black-Scholes model to determine the estimated fair value for purchases under the 2021 ESPP. Black-Scholes models require the input of various assumptions, including the expected life, expected dividend yield, price volatility and risk-free interest rate of the underlying stock. The expected volatility used in calculating the estimated fair value for purchases under the 2021 ESPP is based on the historical volatility of the Company's common stock.

The calculation was based on the following assumptions:

	Three Months Ended March 31, 2024
Strike price (per share)	$4.00
Risk-free interest rate	5.41%
Expected volatility	60.99%
Expected term (in years)	0.5
Expected dividend yield	—

As of March 31, 2024, and December 31, 2023, 904,688 and 659,146 shares of common stock were available for issuance under the 2021 ESPP, respectively. The Company had an outstanding liability of $0.2 million and $0.1 million as of March 31, 2024, and December 31, 2023, respectively, which will be recognized over six months. No shares were issued under the 2021 ESPP during the three months ended March 31, 2024, and 2023, respectively.

11. Income Taxes

The Company recorded income tax expense of zero for the three months ended March 31, 2024 and 2023, respectively. The Company continues to maintain a full valuation allowance.

12. Commitments and Contingencies

Litigation

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 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. No amounts have been accrued as of March 31, 2024. See Note 7 for more information about the EOC License Agreement and its termination.

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 $4.7 million and $5.7 million for expenditures incurred by clinical and contract manufacturing vendors as of March 31, 2024, and December 31, 2023, respectively.

At March 31, 2024, the Company was party to a Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product, as amended effective as of August 1, 2022 and March 31, 2024 (the "Fresenius Agreement"), with Fresenius Kabi that contains specific activities including non-cancellable commitments, minimum purchase commitments, and binding annual forecasts. As of March 31, 2024, there were non-cancellable purchase commitments related to the purchase of inventory for $3.8 million to be paid in 2024.

Mirati Collaboration

In October 2022, the Company 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. In May 2024, the Company announced the mutually agreed upon termination of the collaboration and supply agreement with Mirati and the discontinuation of the Phase 1/2 study. Under the terms of the agreement, Mirati was responsible for sponsoring and operating the Phase 1/2 study and the Company supplied study drug and jointly shared the cost of the study.

The primary objective of this multi-center, single-arm, open-label Phase 1/2 trial was 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 was intended to 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 was built on preclinical data showing enhanced anti-tumor efficacy with the combination of adagrasib and FYARRO relative to either agent alone.

For the three months ended March 31, 2024 and 2023, the Company incurred $0.2 million and $0.4 million in expenses related to the Mirati collaboration, respectively.

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 tumor ("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;
- the anticipated timing of releasing data for current or future clinical trials;
- the anticipated timing of commencement, enrollment, and completion of any current or future clinical trials for FYARRO in additional indications, or any other product candidates we may develop in the future;
- 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, 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 (as defined herein);
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- other factors including but not limited to those detailed under the section entitled "*Risk Factors*."

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.

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 for the year ending December 31, 2023 filed with the SEC on March 13, 2024. 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.

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

Throughout this document we refer to FYARRO (nab-sirolimus, sirolimus protein-bound particles for injectable suspension (albumin-bound)) as FYARRO in the context of commercialization for the treatment of advanced malignant perivascular epithelioid cell tumor (PEComa), investigational use, our clinical trials, regulatory matters such as orphan drug designation, our license agreement with Bristol-Myers Squibb Company and collaboration agreement with Mirati Therapeutics, Inc., all further discussed throughout this document.

Overview

We are a biopharmaceutical company focused on developing and commercializing precision therapies for cancers with alterations in the mTOR pathway, a key regulator of cell growth and cancer progression. Our lead drug product, FYARRO® (sirolimus protein-bound particles for injectable suspension (albumin-bound); *nab*-sirolimus), combines two established technologies - nanoparticle albumin-bound (*nab*) technology and the anti-cancer agent, sirolimus. *Nab*-sirolimus is a potent inhibitor of the mTOR biological pathway with demonstrated anti-cancer activity in our lead indication, advanced malignant perivascular epithelioid cell tumor ("PEComa"), a rare cancer. We believe our approach to utilizing the novel combination of technologies has the potential to produce transformational therapies for patients with cancers beyond PEComa that have known mTOR pathway activation and/or cancers in which other mTOR inhibitors have not been fully exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site. We exclusively license FYARRO, previously called ABI-009, *nab*-sirolimus, from Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, which is a wholly owned subsidiary of Bristol-Myers Squibb Company ("BMS").

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 PEComa. On February 22, 2022, we launched FYARRO in the United States for treatment of advanced malignant PEComa and recognized net product sales of $5.4 million and $5.9 million for the three months ended March 31, 2024 and 2023, respectively. See "Results of Consolidated Operations" for further discussion of our results.

In addition to advanced malignant PEComa, based on exploratory data from our completed Phase 2 registrational study, Advanced Malignant PEComa Trial ("AMPECT trial") and data for FYARRO in other solid tumors with *TSC1* and *TSC2* inactivating alterations, we initiated a registration-directed tumor-agnostic Phase 2 study ("PRECISION1 trial") of FYARRO in patients with malignant solid tumors with alterations of the Tuberous Sclerosis Complex 1 ("*TSC1*") or Tuberous Sclerosis Complex 2 ("*TSC2*") genes. The PRECISION1 trial was opened for enrollment in the United States during the first quarter of 2022 and, on December 14, 2023, we announced results from an interim analysis on the first third of participants in the PRECISION1 trial. This interim analysis included data from the first third of trial participants (n=40) with a minimum of 4.5 months of follow-up, including investigator-assessed response and safety analyzed separately in each of the *TSC1* and *TSC2* arms. We expect to report the two-thirds interim analysis in the third quarter of 2024, with the overall response rate (ORR) analysis of such two-thirds cohort (n=80) based on independent radiological review with a minimum of six months of follow-up for all patients.

Recent Developments

- *PRECISON1 Trial Enrollment and Timing*. In April 2024, we fully enrolled the PRECISION1 trial. The trial is expected to be completed by the end of 2024, with results anticipated in early 2025.
- *Amendment of Fresenius Kabi Agreement*. Effective as of March 2024, we amended our Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product, as previously amended effective as of August 1, 2022 (collectively, the "Fresenius Agreement") with Fresenius Kabi, LLC ("Fresenius Kabi") to, among other things, extend the term of the Fresenius Agreement to July 31, 2024 (or such later date as may be agreed upon between the parties) and amend certain terms related to pricing, forecasting, compliance and our obligation to purchase certain minimum quantities of FYARRO from Fresenius Kabi. Under the Fresenius Agreement, we may purchase FYARRO for either clinical or commercial purposes for use in the United States and Canada.
- *Termination of the Mirati Collaboration*. In May 2024, we announced that, at our request, we and Mirati Therapeutics, Inc. ("Mirati") mutually agreed to terminate our collaboration and supply agreement. We entered into the agreement with Mirati in October 2022 to evaluate the combination of Mirati's adagrasib (KRAZATI®), a $KRAS^{G12C}$ selective inhibitor, and FYARRO in $KRAS^{G12C}$ mutant non-small cell lung cancer ("NSCLC") and other solid tumors. The Phase 1/2 trial has been discontinued as we prioritize the evaluation of *nab*-sirolimus in Phase 2 trials for endometrioid endometrial cancer ("EEC") and in neuroendocrine tumors ("NETs").

BMS License Agreement

We have 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) pursuant to an amended and restated license agreement, dated November 15, 2019, as amended August 31, 2021 (the "BMS License Agreement") with Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, which is a wholly owned subsidiary of BMS. Under the BMS License Agreement, BMS is entitled to receive certain development milestone payments, royalties on net sales from licensed products under the agreement and any sublicense fees. We recorded royalties on net product sales of $0.4 million during the three months ended March 31, 2024 and 2023, under the terms of this agreement. No development payments related to milestones under this agreement were paid during the three months ended March 31, 2024. See Note 7 to the condensed consolidated financial statements for more information about the BMS License Agreement.

On August 30, 2021, the Company and BMS entered into Amendment No. 1 (the "BMS Amendment") to the BMS License Agreement. Under the terms of the BMS Amendment, we paid BMS $5.8 million, representing 50% of the previously outstanding payment obligation under the agreement, following the effective time of our 2021 private investment in public equity (PIPE) financing ("2021 PIPE Financing") that occurred in connection with the closing of the reverse merger of Aerpio Pharmaceuticals, Inc. whereby Aspen Merger Subsidiary, Inc., our wholly-owned subsidiary ("Merger Sub"), merged with and into Aadi Subsidiary, Inc. (formerly known as Aadi Bioscience, Inc. ("Private Aadi")), with Private Aadi surviving as our wholly-owned subsidiary (the "Merger"). Pursuant to the terms of the BMS Amendment, the remaining portion of the previously outstanding payment obligation ($5.8 million), which is recorded on our condensed consolidated balance sheets as due to licensor, is due on the third anniversary of the effective time of the 2021 PIPE Financing (i.e., August 26, 2024), plus any accrued and unpaid interest due thereon.

EOC License Agreement

In December 2020, we entered into the license agreement ("EOC License Agreement") with EOC Pharma (Hong Kong) Limited ("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 BMS License Agreement, we are required to pay 20% of all sublicense fees to BMS. 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 BMS 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 BMS 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 BMS 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. On June 27, 2022, EOC filed a Request for Arbitration with the International Chamber of

Commerce's International Court of Arbitration against us. The arbitration process is ongoing. We intend to defend ourselves vigorously in this matter and pursue all relief to which we are entitled. We are unable to estimate the possible loss or range of loss, therefore no amounts have been accrued as of March 31, 2024. See Notes 7 and 12 to the condensed consolidated financial statements for more information about the EOC License Agreement, its termination and pending arbitration.

Mirati Collaboration

In October 2022, we entered into a collaboration and supply agreement with Mirati to evaluate the combination of Mirati's adagrasib and FYARRO in $KRAS^{G12C}$ mutant NSCLC and other solid tumors. In May 2024, we announced the mutually agreed upon termination of the collaboration and supply agreement with Mirati and the discontinuation of the Phase 1/2 study. Under the terms of the agreement, Mirati was responsible for sponsoring and operating the Phase 1/2 study and we supplied study drug and jointly shared the cost of the study.

The primary objective of this multi-center, single-arm, open-label Phase 1/2 trial was 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 was intended to 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 was built on preclinical data showing enhanced anti-tumor efficacy with the combination of adagrasib and FYARRO relative to either agent alone.

Impact of Negative Global or National Events

Businesses have been and will continue to be impacted by a number of challenging global and national events and circumstances that continue to evolve, including the recent turmoil in the global banking system, public health epidemics, such as the COVID-19 pandemic, extreme weather conditions, increased economic uncertainty, inflation, rising interest rates, and geopolitical instability, including the conflicts in Ukraine, the Middle East and in other countries. The extent of the impact of these events and circumstances on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and scope of the events and their impact on our development activities, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. We have been and continue to actively monitor the potential impacts that these various events and circumstances may have on our business and we take steps, where warranted, to minimize any potential negative impacts on our business resulting from these events and circumstances. For example, as the COVID-19 pandemic developed, we took numerous steps to help ensure the health and safety of our employees. While we have resumed normal operations, any resurgence of the COVID-19 pandemic may cause us to reinstitute certain measures to protect employee safety, including staggered work hours or reduced in-person staffing, that could result in additional disruption and/or delays in our ability to conduct development activities.

We have been and continue to actively monitor our supply chain in light of these challenging global and national events and circumstances, including our third-party materials suppliers. We experienced some supply disruptions due to the COVID-19 pandemic, including closures at certain chip manufacturers, which led to extended lead times for FYARRO and diversion of certain lab materials needed to support COVID-19 relief efforts. While these disruptions have been resolved, we are continuing to monitor our supply chain and contingency planning is ongoing with our partners to reduce the possibility of an interruption to our development activities or the availability of necessary materials.

The ultimate impact of these global and national events and circumstances, either individually or in aggregate, is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to mitigate potentially negative impacts to our business. For example, during the COVID-19 pandemic, our clinical trials were affected by the closure of offices, lack of resources and closure of borders, among other measures being put in place around the world and we made certain modifications to employee travel, with masking and vaccination requirements in our offices, and with our employees working remotely fully or intermittently. Any 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 will continue to actively monitor the rapidly evolving situation related to these global and national events, and may take further actions to mitigate potential negative impacts to our business, and that may alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which these global or national events and circumstances may affect our future business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain. 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 2024.

Key Trends and Factors Affecting Comparability Between Periods

- 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 commercialization of FYARRO, including personnel expenses, sales support, and marketing are included in selling, general and administrative expenses for the three months ended March 31, 2024. We expect these expenses to decrease, as compared to prior periods.
- We have built our research and development team and we expect our research and development costs will increase in 2024, relative to prior periods, as a result of significant expenses related to the PRECISION1 trial which was open to enrollment during the year ended December 31, 2023 and continued enrollment through the three months ended March 31, 2024, as well as our anticipated expenses related to clinical programs for FYARRO in EEC and in NETs. We are currently enrolling patients in (i) a Phase 2 open-label, multi-institutional study to evaluate the efficacy and safety of the combination of FYARRO with letrozole for the treatment of advanced or recurrent EEC and (ii) a Phase 2 multicenter, open-label, single-arm trial to evaluate FYARRO in adult patients with functional or non-functional, well-differentiated, locally advanced unresectable or metastatic NETs of the GI tract, lung, or pancreas who have received ≤2 prior lines of therapy, excluding somatostatin analogs (SSTa).

Liquidity and Capital Resources

As of March 31, 2024, we had $88.3 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 the fourth quarter of 2025. We have incurred net losses in each year since inception and as of March 31, 2024, we had an accumulated deficit of $287.3 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 condensed consolidated 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 Condensed Consolidated Statements of Operations and Comprehensive Loss

Revenue

Product Sales, Net

FYARRO was approved by the FDA in November 2021 for treating adult patients with locally advanced unresectable or metastatic malignant PEComa. On February 22, 2022, we launched sales of FYARRO to specialty distributors ("SDs") 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 requirements. 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 on-hand channel inventory data and sell-through data obtained from the SDs and SP. In arriving at our estimate, we also consider historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related benefits, including share-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.

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 share-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 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.

Cost of Goods Sold

Cost of goods sold consist primarily of royalties paid to BMS, 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 (Expense), Net

Other income, net consists of interest income earned on cash, cash equivalents and short-term investments, partially offset by interest expense related to the convertible promissory notes.

Income Tax Expense

During the three months ended March 31, 2024, and 2023, we recognized no income tax expense on the condensed consolidated statements of operations and comprehensive loss. 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 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Revenue		
Product sales, net	$ 5,353	$ 5,867
Total revenue	5,353	5,867
Operating expenses		
Selling, general and administrative	10,620	11,207
Research and development	13,593	10,956
Cost of goods sold	652	529
Total operating expenses	24,865	22,692
Loss from operations	(19,512)	(16,825)
Other income (expense), net	1,223	1,602
Loss before income tax expense	(18,289)	(15,223)
Income tax expense	—	—
Net loss	$ (18,289)	$ (15,223)

Comparison of the Three Months Ended March 31, 2024 and 2023

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 months ended March 31, 2024 and 2023 were $5.4 million and $5.9 million, respectively. The decrease of sales is a result of distributor ordering patterns and fewer new patient initiations than the historical average.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended March 31, 2024 and 2023, were $10.6 million and $11.2 million, respectively. The decrease of $0.6 million was largely driven by a reduction of $1.1 million in consulting expenses, $0.7 million in legal and other expenses, $0.1 million in commercial and marketing expense, offset by an increase of $1.3 million of personnel expenses primarily related to severance expense due to a workforce reduction primarily related to restructuring of our commercial, medical affairs, and corporate support functions.

Research and Development Expenses

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

	Three Months Ended March 31,	
	2024	2023
Personnel expenses	$ 6,297	$ 6,027
Consultants	415	1,399
External clinical development	4,431	2,694
Clinical drug product manufacturing	2,177	753
Other expenses	273	83
Total research and development expenses	$ 13,593	$ 10,956

Research and development expenses for the three months ended March 31, 2024 and 2023 were $13.6 million and $11.0 million, respectively. The increase of $2.6 million was driven by a $1.7 million increase in clinical development expenses primarily related to the PRECISION1 trial and $1.4 million in clinical drug product manufacturing, offset by a decrease of $0.5 million in headcount, consultants, and other expenses.

Cost of Goods Sold

Cost of goods sold was $0.7 million and $0.5 million for the three months ended March 31, 2024, and 2023, respectively, primarily reflecting royalties incurred on product sold.

Other Income (Expense), Net

Other income, net for the three months ended March 31, 2024 was $1.2 million, compared to other expense, net of $1.6 million for the three months ended March 31, 2023. The change was primarily driven by a decrease in short-term investments held during the three months ended March 31, 2024, compared to the three months ended March 31, 2023.

Liquidity and Capital Resources

Overview

As of March 31, 2024 we had $88.3 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 the fourth quarter of 2025.

We have incurred net losses in each year since inception and as of March 31, 2024, we had an accumulated deficit of $287.3 million. Our net losses were $18.3 million and $15.2 million for the three months ended March 31, 2024 and 2023, respectively. These losses have resulted principally from costs incurred in connection with research and development activities and selling, general and administrative costs associated with our operations. 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 continued commercialization of FYARRO. We expect our expenses, and the potential for losses, to increase as we conduct clinical trials of FYARRO in additional indications and seek to expand our pipeline.

On September 22, 2022, we received funding of $72.2 million, net from a private investment in public equity financing (the “2022 PIPE Financing”) with certain investors (the “2022 PIPE Investors”).

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 March 31, 2024, 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. 333-277018) (the “Shelf Registration Statement”), which was filed with the SEC on February 12, 2024 and which became effective April 30, 2024. No securities have yet been sold under the

Shelf Registration Statement. We filed a prospectus supplement with the SEC on May 3, 2024 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 and 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 thereunder 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 2022 PIPE Financing with the 2022 PIPE Investors for the sale of 3,373,526 shares of our common stock for a price of $12.50 per share and Pre-Funded Warrants to purchase an aggregate of 2,426,493 shares of our 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 2022 PIPE 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 summarizes our cash flows for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	$ (19,653)	$ (21,310)
Net cash provided by investing activities	10,555	16,329
Net cash (used in) provided by financing activities	(10)	8
Net decrease in cash, cash equivalents and restricted cash	$ (9,108)	$ (4,973)

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 selling, 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 three months ended March 31, 2024, cash used in operating activities was $19.7 million and resulted from (i) our net loss of $18.3 million, (ii) a $4.8 million net increase in our operating assets and liabilities, primarily driven by a decrease in accounts payable and accrued liabilities and a decrease in prepaid expenses and other current assets, accounts receivable, and inventory, and (iii) $3.4 million in non-cash adjustments, which were primarily related share based compensation, discount amortization on short-term investments, lease expense, depreciation and amortization.

For the three months ended March 31, 2023, cash used in operating activities was $21.3 million and resulted from (i) our net loss of $15.2 million, and (ii) a $7.8 million net increase in our operating assets and liabilities, primarily driven by an increase in accounts receivable, prepaid expenses, inventory and a decrease in accounts payable and accrued liabilities, and other non-current assets, offset by net non-cash adjustments totaling $1.7 million, which was primarily related to share based compensation, discount amortization on short-term investments, lease expense, depreciation and amortization.

Investing Activities

Cash provided by investing activities for the three months ended March 31, 2024 related to maturities of short-term investments of $18.9 million, offset by purchases of short-term investments of $7.6 million and fixed assets of $0.7 million.

Cash provided by investing activities for the three months ended March 31, 2023 related to maturities of short-term investments of $40.8 million, offset by purchases of short-term investments of $23.1 million and fixed assets of $1.4 million.

Financing Activities

Cash used in financing activities for the three months ended March 31, 2024 related to the deferred offering costs.

Cash provided by financing activities for the three months ended March 31, 2023 related to the exercise of stock options.

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.

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.

Rent expense is being recorded on a straight-line basis. Rent expense related to the Pacific Palisades and Morristown leases was $0.1 million and $0.1 million for the three months ended March 31, 2024 and 2023, respectively. See Note 6 to the condensed consolidated financial statements for details related to future lease payments.

In January 2022, we entered into the Fresenius Agreement with Fresenius Kabi, pursuant to which Fresenius Kabi will manufacture FYARRO for us and we will purchase FYARRO as a finished drug product from Fresenius Kabi, on a purchase order basis. The Fresenius Agreement contains specific activities such as non-cancellable commitments, minimum purchase commitments, or binding annual forecasts. Under the Fresenius Agreement, which is effective through July 31, 2024 (or such later date as may be agreed between the parties in writing), we may purchase FYARRO for either clinical or commercial purposes for use in the United States and Canada.

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, 2023 filed with the SEC on March 13, 2024. There have been no material changes to the critical accounting estimates previously disclosed in our Annual Report on Form 10-K.

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 principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2024, 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 officer, 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, management concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2024.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended March 31, 2024 that have 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 I, “Condensed Consolidated Financial Statements - Note 12” 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 a 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 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 other product candidates that we may develop in the future.
- We may be unable to obtain United States approval for FYARRO for additional indications or any 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 in additional indications or any future product candidates and in such event our business will be substantially harmed.
- Even following approval and commercialization of FYARRO for the advanced malignant perivascular epithelioid cell tumor ("PEComa") indication, 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 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.
- 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.
- 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 and strengthen our intellectual property and our proprietary technologies, including our ability to obtain patent term extension for our product or any future product candidates.
- 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 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, irrespective of outcome.
- Our stock price is volatile.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are a 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 a 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 launched commercially in the United States for treatment of advanced malignant PEComa in February 2022. We generated net product sales for FYARRO of $5.4 million and $5.9 million for the three months ended March 31, 2024 and 2023, 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, the commercialization of FYARRO, hiring personnel, raising capital and providing general and administrative support for these operations. We conducted a Phase 2 registrational study of FYARRO ("AMPECT" trial) for PEComa and completed a rolling New Drug Application (an "NDA") submission for FYARRO in May 2021. 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 data for FYARRO in other solid tumors with truncating Tuberous Sclerosis Complex 1 ("*TSC1*") and Tuberous Sclerosis Complex 2 ("*TSC2*") inactivating alterations, and following discussions with the FDA, we opened enrollment for our registration-directed tumor-agnostic Phase 2 trial ("PRECISION1 trial") in malignant solid tumors harboring *TSC1* or *TSC2* inactivating alterations in the first quarter of 2022. In addition, we are currently enrolling patients in (i) a Phase 2 open-label, multi-institutional study to evaluate the efficacy and safety of the combination of

FYARRO with letrozole for the treatment of advanced or recurrent endometrioid-type endometrial cancer ("EEC") and (ii) a Phase 2 multicenter, open-label, single-arm trial to evaluate adult patients with functional or non-functional, well-differentiated, locally advanced unresectable or metastatic neuroendocrine tumors ("NETs") of the GI tract, lung, or pancreas who have received ≤2 prior lines of therapy excluding somatostatin analogs (SSTa).

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 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 and public offerings of our securities, federal grants and proceeds from licenses. Our net losses were $18.3 million and $15.2 million for the three months ended March 31, 2024 and 2023, respectively. We had an accumulated deficit of $287.3 million as of March 31, 2024, and $269.0 million as of December 31, 2023. 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 $5.4 million for the three months ended March 31, 2024, 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 revenues and expenses. 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 continued 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 price.

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 other product candidates that we may develop in the future.

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 successfully complete discovery, development and eventual commercialization of additional indications (such as *TSC1* and *TSC2*) or any future product candidates, and commercialize FYARRO or any other future product candidates, if approved, in foreign jurisdictions. 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 other product candidates that we may develop in the future, if any, for which there is a commercial market;
- launching and successfully commercializing FYARRO or any other product candidates that we may develop in the future following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;

- maintaining a commercially viable supply of, 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 that we may develop in the future, if approved;
- completing development activities, including clinical trials for FYARRO for *TSC1* and *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 FYARRO 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 FYARRO or any future 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 FYARRO and any future product candidates; and
- 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.

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 this will continue as a result of our ongoing and planned activities, particularly as we seek additional regulatory approval of FYARRO for additional indications, and the continued commercialization of FYARRO for its approved indication (advanced malignant 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 additional indications for FYARRO or any other product candidates that we may develop in the future, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution activities and ongoing compliance activities. Although we launched FYARRO commercially for advanced malignant PEComa in February 2022, 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 additional indications, or any other product candidates we may develop in the future. 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 have incurred, and will continue to incur, additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of March 31, 2024, we had $88.3 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 the fourth quarter of 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 continued commercialization of FYARRO for the advanced malignant PEComa indication, ongoing and planned clinical trials of FYARRO for other indications such as the *TSC1*, *TSC2*, EEC and NETs 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 in additional indications and any future product candidate will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments will 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 further 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 may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from rising inflation and interest rates, monetary policy changes, the COVID-19 pandemic, the conflicts in Ukraine and the Middle East, and otherwise. 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, FYARRO, which has completed development and obtained regulatory approval by the FDA for a single indication. 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 additional 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 for advanced malignant PEComa. 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 continue commercialization of 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, which involved patients for whom there were no approved therapies in the United States. 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 substantial revenues from product sales. We are not permitted to market or promote FYARRO for any non-PEComa indications, until we receive regulatory approval from the FDA and comparable foreign regulatory authorities for any such additional indication, 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 than those demonstrated in our clinical trials;
- the effectiveness of our sales, marketing and distribution efforts;
- 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 success of our commercial sales, including the ongoing 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 PRECISION1 trial;
- 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 exploratory data from the completed AMPECT trial and data for FYARRO in other solid tumors with *TSC1* and *TSC2* inactivating alterations, we initiated PRECISION1, our registration-directed tumor-agnostic Phase 2 study of FYARRO in patients with malignant solid tumors harboring *TSC1* or *TSC2* alterations. We completed a Type B meeting with the FDA in which we discussed the trial design. The PRECISION1 trial is ongoing, with the first patient dosed in March 2022 and the trial full enrolled in April 2024. On December 14, 2023, we announced results from an interim analysis on the first third of participants in the PRECISION1 trial. The trial is expected to be completed by the end of 2024 with results anticipated in early 2025. 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 conflicts in Ukraine and the Middle East, 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, and we could face 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, we could experience significant delays or an inability to successfully commercialize FYARRO for multiple indications in a timely manner or at all, 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/or 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 FYARRO or any other product candidates that we may develop in the future, 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 FYARRO or any other product candidates that we may develop in the future 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 FYARRO or any future approved product, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

FYARRO, or any product candidates we develop in the future for which we may obtain regulatory approval, 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. 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 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. As a result, 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 in additional indications, if approved, 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 (the "American Rescue Plan"), the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs was 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 (the "Inflation Reduction Act"), 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. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. 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 now that we have begun 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. Moreover, coverage policies and third-party payor reimbursement rates, including those of government payors, may change at any time and it is unclear what effect 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, it is possible that 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 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. FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement those goals and their impact on specific clinical programs and the industry are unclear. 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 that we may develop in the future, if approved, from being marketed abroad.

In order to market and sell our products in the European Union and in any other foreign 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 FYARRO and any other product candidates that we may develop in the future, if approved, in any market.

A variety of risks associated with marketing FYARRO and any other product candidates we may develop in the future, if approved, 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, recent conflicts in Ukraine and the Middle East have led to, and could continue to 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 that we may develop in the future, 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 health epidemics, such as the 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 in clinical trials may have received surgical, radiation and chemotherapy treatments and/or 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 FYARRO in additional indications or any future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of FYARRO in additional indications or any future product candidates 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 FYARRO in additional indications or any future 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 their 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 FYARRO or any affected future product candidate, could substantially increase the costs of commercializing our product(s), including FYARRO, and significantly impact our ability to successfully commercialize FYARRO or any other product candidates that we may develop in the future, if approved, 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 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 any future 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 FYARRO or any future product candidates 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, 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 FYARRO or any other product candidates that we may develop in the future 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.

We are subject to risks relating to open-label clinical trials.

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 biases, including a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with FYARRO or any future 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, independent radiographic or clinical review, and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, such as our interim analysis on the first third of participants in the PRECISION1 trial, which was announced on December 14, 2023. 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, independent radiographic or clinical review, 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 commercial sales or 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* and *TSC2* study are screened using genomic information to identify alterations in the *TSC1* or *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* or *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 FYARRO or any future 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 FYARRO or any future 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 FYARRO and any other product candidates that we may develop in the future and jeopardize our ability to obtain regulatory approval for the sale of FYARRO in additional indications or any future 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. For example, in the third quarter of 2023, we commenced a Phase 2 open-label, multi-institutional study to evaluate the efficacy and safety of the combination of FYARRO with letrozole for the treatment of advanced or recurrent EEC. Patients may not be able to tolerate FYARRO or any of our future product candidates in combination with other therapies or dosing of FYARRO or any of our future product candidates 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, or 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 products, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which FYARRO or any future 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 FYARRO or any future 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 FYARRO or any future product candidates in combination with one or more other 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 FYARRO or any future product candidate in combination with any such unapproved 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 FYARRO or any future 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 FYARRO or any future 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 FYARRO in additional indications or any other product candidates that we may develop in the future.

Additionally, if the third-party providers of therapies or therapies in development used in combination with FYARRO or any future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of FYARRO in additional indications or any future product candidates, if approved, 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, due to our 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 indications for FYARRO could result in our focus on particular indications for FYARRO 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 FYARRO or any future 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 FYARRO or any future product candidates. In addition, FYARRO or any future product candidates 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 *TSC1* or *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* and *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.

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 on November 22, 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 other product candidates that we may develop in the future and, as a result, may be unable to commercialize FYARRO in additional indications or any future product candidates and in such event 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.

Disruptions at the FDA and other agencies, such as previous delays or disruptions due to the COVID-19 pandemic, travel restrictions, and staffing shortages, may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In response to the COVID-19 pandemic, after 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 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 has largely caught up with domestic preapproval inspections, it continues to work through its backlog of foreign inspections. 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.

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 for the treatment of advanced malignant PEComa, 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. Other than FYARRO, we have not obtained regulatory approval for any product candidate, and it is possible that none of our additional 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 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 are currently conducting our PRECISION1 trial of FYARRO in the United States and South Korea, but we may conduct the trial in other countries in the future. 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.

We are subject to risks relating to regulatory uncertainty in foreign jurisdictions.

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, as set forth in the Protocol on Ireland and Northern Ireland and as amended by the Windsor Framework, which will be implemented in Northern Ireland on January 1, 2025. 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. In June 2023, FDA announced a new voluntary pilot program through which drug manufacturers can provide to the FDA the diagnostic test performance information used to enroll patients into clinical trials for drug approval. Based on assessment of the performance information, the FDA will publish the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug to help laboratories identify specific biomarkers for their development of laboratory-developed tests, or LDTs, and to ensure more consistent performance of these tests for drug selection and improved cancer patient care. In October 2023, the FDA published a proposed rule that proposes to phase out its enforcement discretion for most LDTs and to amend the FDA's regulations to make explicit that in vitro diagnostics are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the diagnostic product is a laboratory. If we or our collaborators develop any LDTs, such products would be subject to FDA regulation as medical devices, and we would need to invest significant time and resources to ensure ongoing compliance with FDA quality system regulations and other post-market regulatory requirements. In January 2024, FDA announced its plans to reclassify certain high-risk in vitro diagnostics, including companion diagnostics, as Class II (or moderate risk) devices. We will continue to evaluate the impact of FDA guidance and other developments in the diagnostic space. 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* or *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* or *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* or *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.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the orphan drug exclusivity. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

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 and orphan drug exclusivity from the FDA for FYARRO for the treatment of advanced malignant PEComa. We may be unable to obtain orphan drug designation or orphan drug exclusivity 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. The Food and Drug Omnibus Reform Act made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. In March 2023, the FDA issued a draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for more robust efficacy and safety assessment. To the extent the FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which can have an adverse effect on our business and operations.

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. Some of the provisions of the ACA have been subject to judicial and Congressional challenges, and 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.

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 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, 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. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges as well as 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.

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 2032, unless additional congressional action is taken. 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.

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. Additionally, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. 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. Further, if the Supreme Court reverses or curtails the *Chevron* doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA's authority, lead to uncertainties in the industry, and disrupt FDA's normal operations, which could delay FDA's review of our marketing applications.

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 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. Additionally, the UK has implemented legislation that substantially implements the GDPR, the UK GDPR, which provides for similar obligations and provides for penalties for noncompliance of up to the greater of £17.5 million or four percent of worldwide revenues. The GDPR and UK 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 and UK GDPR. This may be onerous and if our efforts to comply with the GDPR, UK GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union and United Kingdom.

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, and subsequently was amended and supplemented by the CPRA, 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. Numerous other states in the U.S. have proposed or enacted similar legislation. While the CCPA and many other similar state laws exempt some data regulated by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and certain clinical trials data, the CCPA and such other laws, to the extent applicable to our business and operations, may increase our compliance costs and potential liability. Further, some states have enacted more specific legislation, such as Washington's enactment of the My Health, My Data Act, which includes a private right of action. The U.S. federal government is also contemplating federal privacy legislation. The evolving trend toward more stringent privacy legislation in the United States, including the foregoing laws and regulations and the potential for future laws and regulations,could increase our compliance costs and potential liability and adversely affect our business.

It is possible that the GDPR, UK GDPR, CCPA, CPRA, or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our policies and practices. We cannot guarantee that we are in compliance with all such applicable data protection laws and regulations, and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations. Furthermore, other jurisdictions outside the EU are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase our compliance costs and the risks associated with noncompliance. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, and our efforts to comply with the evolving data protection rules may be unsuccessful. Our actual or alleged non-compliance could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures, and systems.

Our actual or perceived failure to adequately comply with applicable laws and regulations or other actual or asserted obligations relating to privacy and data protection, or to protect personal data and other data we process or maintain, could result in regulatory enforcement actions against us, including fines, imprisonment of company officials and public censure,

claims for damages by affected individuals, other lawsuits or reputational and damage, all of which could materially affect our business, financial condition, results of operations, and growth prospects.

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.

If a prolonged government shutdown occurs or if the FDA's normal operations are disrupted, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, 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;
- 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 GDPR, the UK GDPR, and state laws and regulations, including general legislation such as the CCPA, and sector- or subject matter-specific laws and regulations, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways. Many state laws in the U.S. are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state and other laws and regulations and if we fail or are alleged to comply with an applicable requirement of any of these laws or regulations, we could be subject to claims, demands, and litigation initiated by private individuals or entities, regulatory investigations and other proceedings, and fines, penalties, and other liabilities.

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 alleged or 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 consequences, 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. 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.

Our business activities may be subject to 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 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 in 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, escalation in conflicts in Ukraine and the Middle East, 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.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

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, as amended effective as of August 1, 2022 and March 31, 2024 (collectively, 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 is effective through July 31, 2024 (or such later date as may be agreed between the parties in writing). Under the Fresenius Agreement, 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 negatively impact

the 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 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 withdraw 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 we most recently amended effective as March 31, 2024 to, among other things, extend the term of the Fresenius Agreement to July 31, 2024 (or such later date as may be agreed upon between the parties) and amend certain terms related to pricing, forecasting, compliance and our obligation to purchase certain minimum quantities of FYARRO from Fresenius Kabi. 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, which is a wholly owned subsidiary of Bristol-Myers Squibb Company ("BMS") pursuant to which we have licensed exclusive global rights to intellectual property and know-how related to FYARRO. 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 below 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 (as defined herein) exclusive rights to develop and commercialize FYARRO in the EOC Territory (as defined below).

Under the EOC License Agreement (as defined herein), 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"). The EOC License Agreement was terminated effective June 27, 2022, and EOC initiated a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against us on the same date. 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 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. See Notes 7 and 12 to the condensed and consolidated financial statements for more information about the EOC License Agreement, its termination and resulting arbitration.

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 FYARRO in additional indications or any future 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 FYARRO in additional indications or any future 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 FYARRO in additional indications or any future 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 FYARRO in additional indications or any future 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 FYARRO or any future 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 de-emphasize 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 FYARRO or any other product candidates that we may develop in the future 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 FYARRO or any other product candidates that we may develop in the future;
- 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 the matter is currently in arbitration. See Notes 7 and 12 to the unaudited consolidated financial statements for more information about the EOC License Agreement, its termination, and resulting arbitration. 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 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.

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. On November 9, 2022, we announced the transition of Neil Desai, our founder, director, President and Chief Executive Officer to Executive Chairman, and the appointment of Brendan Delaney, our Chief Operating Officer, to President and Chief Executive Officer, each effective January 1, 2023. Following such transition, on March 3, 2023, we announced Mr. Delaney's resignation as President and CEO, effective March 14, 2023, and the appointment of Scott Giacobello, our Chief Financial Officer to Interim CEO and President, effective March 15, 2023. Mr. Giacobello served as our Interim CEO and President until the appointment of David Lennon as President and CEO, effective October 2, 2023, and Mr. Giacobello continued in his role as Chief Financial Officer. These leadership transitions, as well as future other senior management changes, could disrupt and have

a detrimental effect on our business. 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 that we may develop in the future, 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, when 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 or 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 March 31, 2024, we had 75 full-time employees, including 51 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 we may develop in the future, while complying with any contractual obligations to contractors and other third parties that 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, or use or other processing 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 and incidents 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 systems and 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. These risks may be heightened due to the increasing number of our and our vendors' and contractors' personnel working remotely. Further geopolitical events such as wars and conflicts may increase the cybersecurity threats we and the third parties we work with face. Any disruption or security breach or incident resulting in a loss, destruction, unavailability, or unauthorized alteration, dissemination, or other processing 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, have prevented or will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, or unauthorized alteration, dissemination, or other processing of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, any such event that were to occur and cause interruptions in our operations could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss, unauthorized alteration, or unavailability

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, interruptions or other disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, disclosure, or other processing 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 or is perceived to lead to unauthorized access, use, disclosure, or other processing of individually identifiable health information or personal information, including such 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 such 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 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. 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 or incident. 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. Any disruption or security incident resulting or perceived to result, in any loss, destruction, or unauthorized alteration or other processing of, or damage to, our data (including personal information and other information relating to individuals, and our confidential or proprietary information or that of third parties), we could be exposed to claims, demands, litigation and governmental investigations and other proceedings, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines, penalties, and other liabilities.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach of, or security incident of, or impacting, our systems or third-party systems where information important to our business operations or commercial development is stored or otherwise processed. 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.

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. 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. As of December 31, 2023, 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 $187.2 million, $44.1 million of which will begin to expire in 2030 and the remaining $143.1 million do not expire. We also have state NOL carryforwards of approximately $92.0 million available as of December 31, 2023, 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. Limitations may also apply to state NOLs under state law.

Changes in tax laws 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, beginning in 2022, the legislation commonly known as the Tax Cuts and Jobs Act of 2017, or the Tax Act, requires U.S. research and experimental expenditures to be capitalized and amortized ratably over a five-year period. Any such expenditures attributable to research conducted outside of the United States must be capitalized and amortized over a 15-year period. Further, in August 2022, the United States 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.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect and strengthen our intellectual property and our proprietary technologies, including our ability to obtain patent term extension for our product or any future product candidates.

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 twelve (12) 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 other product candidates that we may develop in the future 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 FYARRO or any other product candidates we may develop in the future. 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 file any patent application related to our product or product candidates or 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 for advanced malignant PEComa. 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 exclusively licensed at least twelve (12) 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.

Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which significantly impacts European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the "UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of these changes.

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 any future 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 experience 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 that we may develop in the future, 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.

General Risks

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

As described in Note 12 (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 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 on August 26, 2021 through March 31, 2024, the closing price for our common stock ranged from a low of $1.59 to a high of $33.00 per share. 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 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;
- 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;
- 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 turmoil in the global banking system, deteriorating market conditions due to investor concerns regarding inflation and conflicts in Ukraine and the Middle East;
- 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, or the anticipation thereof;
- 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 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.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, and expenses that are not readily apparent from other sources. For example, management makes judgments and assumptions regarding our product sales based on our interpretation of ASC Topic 606, Revenue from Contracts with Customer ("Topic 606"). The revenue standard is principle-based, and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgements relating to our

critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

We will continue to incur significant increased costs and management resources as a result of operating as a public company.

As a public company, we will continue to incur significant legal, accounting, compliance and other expenses that we did not incur as a private company and these expenses may increase even more since we are no longer an "emerging growth company." Our management and other personnel will need to devote a substantial amount of time and incur significant expense in connection with compliance initiatives. As a public company, we will continue to bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws. In addition, regulations and standards relating to corporate governance and public disclosure, including the SOX, and the related rules and regulations implemented by the SEC and The Nasdaq Stock Market LLC, have increased legal and financial compliance costs and will make some compliance activities more time-consuming. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members for our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

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.

Sales of a substantial number of shares of our common stock in the public market, including by our existing stockholders, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock.

On February 12, 2024, we filed a universal shelf registration statement on Form S-3 (File No. 333-277018) (the "Shelf Registration Statement"), which became effective on April 30, 2024. No securities have yet been sold under the Shelf Registration Statement. We have established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. 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 the Shelf Registration Statement or any future registration statement on Form S-3 that we may file with the SEC will be limited to raising an aggregate of one-third of our public float in any 12-month period.

Our directors and employees may sell our stock through 10b5-1 trading plans or in the market during open windows under our insider trading policy without such plans in place. Sales of our common stock by our officers, directors, holders of 5% or more of our capital stock and their respective affiliates, and employees could be perceived negatively by investors or cause downward pressure on our common stock and cause a reduction in the price of our common stock as a result. We have also registered shares of our common stock that we may issue under our employee equity incentive plans. These shares will be able to be sold freely in the public market upon issuance.

SEC regulations limit the amount of funds that we can raise during any 12-month period pursuant to a shelf registration statement on Form S-3.

SEC regulations limit the amount that companies with a public float of less than $75 million may raise during any 12-month period pursuant to a shelf registration statement on Form S-3. As of the filing of this Quarterly Report on Form 10-Q, we are subject to General Instruction I.B.6 to Form S-3, referred to as the baby shelf rules. Under these regulations, the amount of funds we can raise through primary public offerings of securities in any 12-month period using a registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by non-affiliates of the Company. Therefore, we will be limited in the amount of proceeds we are able to raise by selling shares of our common stock using a Form S-3 until such time as our public float exceeds $75 million. Furthermore, if we are required to file a new registration statement on another form, it may incur additional costs and be subject to delays due to review by the SEC staff.

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 own 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 market and global economic conditions as a result of multiple global events, such as the COVID-19 pandemic, adverse developments affecting the financial services industry, the conflicts in Ukraine and the Middle East, increasing interest rates and general economic downturns, could adversely affect our business, financial condition or results of operations.

While the potential economic impact brought by multiple adverse global circumstances, such as the COVID-19 pandemic, conflicts in Ukraine and the Middle East, potential uncertainty related to Taiwan and its relationship with China, increasing interest rates, adverse developments affecting the financial services industry and general economic downturns are difficult to assess or predict, both as to magnitude and duration, these events have resulted in, and may continue to result in, extreme volatility and disruptions in the capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. Additionally, our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for FYARRO or our any of our future 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 the Middle East, 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, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the “FDIC”), as receiver, and on March 27, 2023, First-Citizens Bank & Trust Company assumed all of SVB’s customer deposits and certain other liabilities and acquired substantially all of SVB's loans and certain other assets from the FDIC. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each

swept into receivership. While we only had a minimal amount of our cash directly at SVB and, since that date, the FDIC has stated that all depositors of SVB would be made whole, and First-Citizens Bank & Trust Company has assumed our deposits from SVB, there is no guarantee that the federal government would guarantee all depositors as they did with SVB depositors in the event of further bank closures and continued instability in the global banking system may adversely impact our business and financial condition.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

Our operations and performance may be affected by political or civil unrest or military action, including the current conflicts in Ukraine and the Middle East, 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.

Additionally, there is ongoing uncertainty regarding the federal budget and federal spending levels, including the possible impacts of a failure to increase the "debt ceiling." Any U.S. government default on its debt could have broad macroeconomic effects that could, among other things, disrupt access to capital markets and deepen recessionary conditions. Further, as of March 31, 2024, we had cash, cash equivalents and short-term investments of $88.3 million, consisting of U.S. government treasury bills, commercial paper, corporate debt securities, and government agency bonds. Any default by the U.S. government or credit downgrade of the securities we hold could impact the liquidity or valuation of our investments.

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, cyberattacks, geopolitical tensions, including those related to the conflicts in Ukraine and the Middle East 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.

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 (i) as of the last business day of its most recently completed second fiscal quarter has an aggregate market value of the company's voting stock held by non-affiliates, or public float, of less than $250 million or (ii) for the most recently completed fiscal year has less than $100 million in revenue and as of the last business day of its most recently completed second fiscal quarter has less than $700 million in public float. 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.

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.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Securities Trading Plans of Directors and Executive Officers

During our last fiscal quarter, none of our directors or officers, as defined in Rule 16a-1(f), adopted and/or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408.

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 (File No. 001-38560) filed with the SEC on August 27, 2021).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on December 7, 2022).
10.1*+	Amendment No.2 to the Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product, dated April 1, 2024, by and between Aadi Bioscience, Inc. and Fresenius Kabi, LLC
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 Exhibits 32.1 and 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 it by reference.

\+ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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: May 8, 2024

By: */s/ David J. Lennon*

David J. Lennon, Ph.D.
Chief Executive Officer and President
(Principal Executive Officer)

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Exhibit 10.1

AMENDMENT NO. 02 to
NEGOTIATED PURCHASE ORDER TERMS AND CONDITIONS
FOR CLINICAL AND COMMERCIAL PRODUCT

This Amendment No. 02 to the Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product, with a last signed date of January 13, 2022, (**"Amendment"**) is made effective as of March 31, 2024 ("**Amendment Effective Date**") by and between Fresenius Kabi, LLC, a Delaware company having a principal place of business at Three Corporate Drive, Lake Zurich, IL 60047 ("**FRESENIUS KABI**"), and AADi Bioscience, Inc., a Delaware corporation having a principal address at 17383 Sunset Blvd., Suite A 250, Pacific Palisades, CA 90272 ("**AADI**" or "**Customer**"). Fresenius Kabi and AADI may hereafter be referred to collectively as the "**Parties**" and individually as a "**Party**."

WHEREAS, FRESENIUS KABI and AADI are Parties to the Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product with a last signed date of January 13, 2022, as amended by Amendment 01 effective as of August 1, 2022 ("**Agreement**" or "**Negotiated Terms and Conditions for Commercial Product**"); and

WHEREAS, the Parties mutually desire to amend, modify and restate certain terms and conditions of the Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants herein contained, it is mutually agreed as follows:

1. DEFINITIONS

Unless otherwise defined herein, capitalized words in this Amendment shall have the meaning attributed to them in the Agreement.

2. AMENDMENTS

The Parties agree that, as of the Amendment Effective Date, the Agreement is further amended as set forth in this Section 2.

2.1 The second paragraph on page 1 of the Agreement shall be deleted and replaced by the following new paragraph:

"AADI shall submit firm purchase orders, subject to the Negotiated Terms and Conditions for Commercial Product, to FRESENIUS KABI pursuant to the Forecast (defined below) specified in Exhibit G for (i) any clinical or commercial products manufactured at [***] batch size, defined in Exhibit A for the Territory ("**Product**") and (ii) any products manufactured at [***] batch size ("[***] **Product**"). Such purchase orders are to be submitted by AADI according to the Forecast in Exhibit G (i) no later than [***] prior to the intended manufacturing date for Product and [***] Product as specified in the Forecast; or (ii) no less than [***] prior to the intended manufacturing date if AADI requests a manufacturing date in [***]; with the understanding that as relevant to this subparagraph (ii), the Parties agree that manufacture will only occur in [***] if, at least [***] prior to AADI's submission of the required purchase order, all implementation activities related to manufacture as described in Amendment 02 of AAD-ABI-DEV-03 are completed and the Parties have agreed to testing protocol. Pursuant to this Agreement, each purchase order shall specify AADI's purchase order number, Product and/or [***] Product being ordered, the requested manufacturing date according to the binding Forecast, the requested delivery date (subject to the conditions set forth in this Section), delivery instructions, price, shipping and invoice address of AADI or AADI's designated recipient, and other applicable invoice information as agreed to by the Parties in writing. The requested delivery date shall be no earlier than [***] after the requested manufacturing date (considering [***] for batch record review by AADI and [***] for one additional batch record review by FRESENIUS KABI based on AADI comments), provided that no regulatory approval is required for release of such Product or [***] Product. For purposes of this Agreement, reference to manufacturing date(s) or date of manufacture means the date on which the water draw is taken for the human albumin formulation for the particular Product or [***] Product.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Exhibit 10.1

All purchase orders shall be in writing and shall be confirmed or declined by FRESENIUS KABI in writing at the latest [***] after receipt of each firm purchase order. If FRESENIUS KABI cannot agree to AADI's proposed manufacturing date or delivery date, FRESENIUS KABI may decline the purchase order, and the Parties shall negotiate in good faith a new manufacturing or delivery date. In the event an alternative manufacturing date is not commercially reasonable within the term of the Agreement for any reason (including but not limited to the unavailability of completed method implementation or documentation required for manufacture), FRESENIUS KABI shall not be obliged to manufacture any batches outside the term of the Agreement or with a manufacturing date outside the term of the Agreement. FRESENIUS KABI may elect not to manufacture Product and/or [***] Product for any confirmed purchase orders if any outstanding invoice(s) payable by AADI exceed [***] (USD). In such instance, the Parties shall agree on an alternative manufacturing date as soon as AADI has settled the outstanding invoice(s)."

2.2 The last sentence of Section 1 (Purchase Order) of the Agreement shall be deleted and replaced by the following sentences:

"Notwithstanding anything to the contrary, AADI agrees that for (i) any Product or (ii) any [***] Product, specified in the Forecast in Exhibit G and still requiring regulatory approval for clinical or commercial release as of the manufacturing date, FRESENIUS KABI may invoice and AADI shall pay FRESENIUS KABI, based on the purchase order for Product or [***] Product under this Agreement, [***] of monies owing for such batches on the manufacturing date, and the remaining monies upon availability of analytical testing data and closure of deviations with AADI acceptance, based on final yield or on filling yield, if Product or [***] Product is packaged only after regulatory approval, independent of the availability of regulatory approval for such batches. FRESENIUS KABI shall base the [***] it invoices under this Section on the target number of vials identified in the relevant purchase order submitted under this Agreement. If the actual yield delivered to AADI under the purchase order falls below the amount invoiced to AADI under this Section, FRESENIUS KABI shall credit AADI the difference between the actual yield and invoiced amount at the time the relevant Product or [***] Product has received approval, is released and been delivered to AADI. Invoices shall be payable by AADI within [***] days from receipt of the applicable invoice."

2.3 Section 2 (Entire Agreement) of the Agreement shall be deleted and replaced by the following new Section 2:

"2) Entire Agreement: Except as expressly set forth in writing executed by the Parties, the purchase order along with these Negotiated Terms and Conditions for Commercial Product, the Quality Agreement, and the Side Letters entered on July 16, 2020 and October 31, 2023 between AADI, FRESENIUS KABI and Abraxis Bioscience, LLC, a Delaware limited liability company and wholly owned subsidiary of Celgene Corporation, constitute the entire agreement between AADI and FRESENIUS KABI regarding the subject matter of the purchase order, and no modification or termination hereof shall be binding unless agreed to in writing and signed by a duly authorized officer or duly authorized representative of AADI and FRESENIUS KABI. For clarity, the Parties entered into Negotiated Purchase Order Terms and Conditions, with a last signed date of July 27, 2020, and Amendment 01 thereto, effective on October 27, 2020 ("**Prior NTCs**") applicable to the manufacture and supply of Product for development and clinical uses; the Prior NTCs shall continue in full force and effect regarding the subject matter therein. The Negotiated Terms and Conditions for Commercial Product shall supersede and control any general terms and conditions in any form of purchase order or any other business forms used by the Parties for the purposes of ordering, acknowledging, invoicing or shipping Product. Any additional, different, or inconsistent general terms and conditions contained in any purchase order, form, acknowledgment, acceptance, or confirmation are hereby objected to and rejected. Subject to the foregoing, the Parties may elect to have these Negotiated Terms and Conditions for Commercial Product superseded in their entirety by the terms and conditions of the commercial manufacturing agreement, if executed."

2.4 Section 3 (Forecasts and Facility Relocation) shall be deleted and replaced by the following new Section 3:

"3) Forecasts and Facility Relocation:

a. FRESENIUS KABI acknowledges that it has received from AADI an updated forecast for required manufacturing slots ("**Product Manufacturing Timing Estimates**" or "**Forecast**") setting forth AADI's good faith estimate of its expected timing of manufacture of Product and [***] Product for the period beginning on the Effective Date and concluding [***] as specified in Exhibit G.

b. The Forecast shall be binding, and AADI shall submit an appropriate purchase order for the Product and [***] Product, respectively, consistent with the second paragraph on page 1 of the Agreement. Changes to the Forecast, if any, need to be in the form of an amendment to the Agreement executed by AADI and FRESENIUS KABI.

c. The FRESENIUS KABI facility for manufacture of Product and [***] Product is located in Grand Island, NY. Part or all of the release testing of Product and [***] Product will be performed by the FRESENIUS KABI facility in Melrose Park, IL and as specified in detail in the Quality Agreement.

d. FRESENIUS KABI shall provide manufacturing capacity per calendar month for a total of [***] batches including for (i) Product, (ii) any [***] Product, and (iii) any batches to be manufactured as part of the Line 13 development agreement (being negotiated between the Parties). For calendar months with production shut down(s), FRESENIUS KABI shall have flexibility to move manufacture of [***] batch to an alternate calendar month. In the event that demand by AADI exceeds the manufacturing capacity, the Parties shall negotiate in good faith how to proceed. For clarity, there is no obligation for FRESENIUS KABI to provide any manufacturing capacity after the term of this Agreement.

e. FRESENIUS KABI and AADI shall use commercially reasonable efforts to develop a detailed timeline and plan to transfer manufacture of Product or [***] Product to Line 13 of FRESENIUS KABI's manufacturing facility at Grand Island, NY."

2.5 Section 7 (Quality; Warranty), shall be deleted and replaced by the following new Section 7:

"7 (Quality; Warranty):

a. The Parties have entered into a Fresenius Kabi - Aadi Bioscience Quality Agreement dated 28 July, 2020 (the "**Quality Agreement**"). The Parties shall use good faith efforts to enter into an amendment of the Quality Agreement prior to the GMP manufacture of any Product or [***] Product by FRESENIUS KABI and prior to the confirmation of the purchase order related to GMP manufacture of any Product or [***] Product. Manufacture and supply of all Product or [***] Product under this purchase order shall be subject to the Quality Agreement. If there is a conflict between the terms of this purchase order and the Quality Agreement, the Quality Agreement shall govern in relation to technical and quality issues and this purchase order shall govern for all other purposes.

b. FRESENIUS KABI represents, warrants and agrees that:

i. upon delivery of Product, and provided that regulatory approval for the Product does not modify the Specifications as of the Effective Date, the Product shall conform to the Specifications and shall have been manufactured in accordance with GMP, all applicable laws, rules and regulations, and the Quality Agreement. Notwithstanding anything to the contrary, the representations and warranties provided by FRESENIUS KABI in this Agreement do not apply to Product or [***] Product requiring regulatory approval for clinical or commercial release at the time of the manufacturing date. Further, FRESENIUS KABI does not guarantee regulatory approval will be obtained for any such Product or [***] Product and shall not be liable or responsible for any batch costs to AADI or any other third party in the event Product or [***] Product requiring regulatory approval for clinical or commercial release at the time of the manufacturing date, fails to receive regulatory approval.

ii. FRESENIUS KABI will maintain all government registrations, permits, licenses and approvals necessary for FRESENIUS KABI to manufacture and supply Product or [***] Product to AADI for commercial use in the Territory or otherwise perform its obligations under this purchase order, provided that AADI obtains all required regulatory approval for the Product or [***] Product,

iii. title to the Product or [***] Product will pass free and clear of any security interest, lien or other encumbrance, and

iv. neither FRESENIUS KABI nor any of its employees have been "debarred" or subject to a similar sanction from any regulatory authority nor have any debarment proceedings against FRESENIUS KABI or any of its employees been commenced. FRESENIUS KABI will promptly notify AADI in writing if any government registrations, permits, licenses and approvals necessary for FRESENIUS KABI to manufacture and supply Product to AADI are revoked or suspended or if FRESENIUS KABI or any of its employees are debarred. FRESENIUS KABI shall not engage any subcontractor to perform any services under this purchase order without the prior written consent of AADI.

c. AADI represents, warrants and agrees that:

i. The performance of AADI's responsibilities under this Agreement and AADI's use of the Products and or [***] Product comply with all Applicable Laws;

ii. the Supplied Materials are, at the time of delivery, free from liens, defects, and in accordance with authorization from all relevant health/regulatory authorities and with all specifications agreed to by the Parties for the Supplied Materials;

iii. to AADI's knowledge, the use of the AADI background intellectual property in the conduct and the provision of the Services will not violate any patent, trade secret or other proprietary or intellectual property rights of any third party that has not consented to the provision of the Services and it will promptly notify FRESENIUS KABI in writing should it become aware of any claims asserting such violation; and

iv. AADI has not and will not use or commercialize Product and or [***] Product purchased hereunder outside the Territory.

Except as expressly set forth in this Agreement, neither Party makes any representations or extends any warranties of any kind, either express or implied, including warranties of merchantability, fitness for a particular purpose, or non-infringement.

2.6 Section 12 (Payment) shall be deleted and replaced by the following new Section 12:

"12) Payment: Except to the extent there exists a good faith dispute with an invoice amount, AADI shall pay each invoice within [***] from the date of receipt of the applicable invoice in US Dollars; an invoice shall not be issued until the release of the applicable Product or [***] Product by AADI as agreed upon in the Quality Agreement, unless otherwise permitted in this Agreement. If applicable, such release shall be provided by AADI within [***] of receipt of all documents from FRESENIUS KABI in accordance with AADI's requirements as specified in the Quality Agreement but considering no more than one review cycle of documents. Unless otherwise set forth in these Negotiated Terms and Conditions for Commercial Product (including Exhibits A through G, as well as any future exhibits thereunder), FRESENIUS KABI shall invoice AADI for [***] of the total value of the purchase order no earlier than [***] prior to the manufacturing date of Product or [***] Product covered by such invoice, and shall invoice AADI for the remaining [***] of the total value of the purchase order upon delivery of the final released Product, unless otherwise agreed between the Parties in writing.

Notwithstanding anything to the contrary in this Agreement, FRESENIUS KABI may invoice any Product or [***] Product (i) that has been released by AADI as agreed in the Quality Agreement but is not delivered to AADI within [***] after its release, or (ii) if the no deviations are triggered by AADI within [***] from the date on which FRESENIUS KABI has provided the relevant executed batch record and release testing data, or (iii) if FRESENIUS KABI has provided executed batch records and release testing data to AADI for Product but regulatory approval for a Product Change has not been received from the relevant regulatory authority.

Such invoice shall be paid by AADI in U.S. Dollars within [***] from the date of receipt of the applicable invoice. In the event the Parties agree in writing that Product is stored for an agreed period of time at FRESENIUS KABI after release, fees as described in Section 14 apply."

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Exhibit 10.1

2.7 The following sentences shall be added to the end of Section 17 (Inspection and Acceptance) as new separate paragraphs:

This Section 17 shall apply only for Product already approved by the respective regulatory authority at the time of the manufacturing date.

Notwithstanding anything to the contrary in this Agreement, FRESENIUS KABI shall not be obliged to replace or manufacture any batches outside the term of the Agreement or with a manufacturing date outside the term of the Agreement.

2.8 Section 31 (Term; Termination) shall be deleted and replaced by the following new Section 31:

31) "**Term; Termination**: The term of this Agreement begins upon FRESENIUS KABI's acceptance of the purchase order and continues until July 31, 2024, subject to the terms that survive expiration or termination of this Agreement (i.e., Sections 2, 4, 19, 21, and 26-31), provided that purchase orders have been placed by AADI pursuant to the second paragraph on page 1 and the terms of this Agreement.

Upon expiration or termination of this Agreement, no Party shall have any obligation to make any further payments to the other, except for amounts accrued prior to expiration or termination. Further, any purchase orders for Product or [***] Product confirmed by FRESENIUS KABI with a batch manufacturing date prior to expiration or termination of the term of this Agreement shall be delivered by FRESENIUS KABI and shall be paid by AADI in full pursuant to this Agreement. Except as otherwise agreed upon by the Parties and except for any purchase order AADI may submit requesting a manufacturing date in [***], AADI may terminate a purchase order submitted under this Agreement within [***] of FRESENIUS KABI's confirmation of the purchase order. AADI may not terminate a confirmed purchase order under this Agreement after such [***] period."

2.9 The Agreement shall be amended to add the following new Section 32 (Development Risks):

32) Development Risks: The Parties agree and understand that Product or [***] Product requiring regulatory approval for clinical or commercial release at the time of the manufacturing date is subject to special development risks and FRESENIUS KABI cannot guarantee development or release success. The Parties agree and understand that neither Party warrants or guarantees that a marketable product shall result in Product or [***] Product. In the case of changes in manufacturing process or Specifications, both Parties shall use good faith efforts to come to a mutual agreement on the further proceeding, amended timelines and additional costs, provided that FRESENIUS KABI shall not be required to continue performance under this purchase order if the Parties are unable to come to such mutual agreement.

2.10 The Agreement shall be amended to add the following new Section 33 (Inspection and Acceptance for Product and [***] Product still requiring regulatory approval for clinical or commercial release at the time of the manufacturing date):

33) Inspection and Acceptance for Product and [***] Product still requiring regulatory approval for clinical or commercial release at the time of the manufacturing date (together "**Non-Approved Product**"). Notwithstanding anything to the contrary in the Agreement:

FRESENIUS KABI is only liable for costs of Supplied Materials if Non-Approved Product did not comply to Non-Approved Product Specifications due to: (i) FRESENIUS KABI's failure to comply with GMP for the relevant regulatory authority; (ii) FRESENIUS KABI's gross negligence or willful misconduct; or (iii) FRESENIUS KABI's negligent failure to follow documented procedures agreed between the Parties or required under GMP for manufacture, testing and release of the Non-Approved Product, including the testing and release requirements for raw materials set forth in the Quality Agreement. In the event of (i) or (iii) under this Section, Section 21 (Limitation on Liability) applies. No additional liability in the event of recalls of Non-Approved Product shall apply.

Except for the circumstances described under subparagraph (i), (ii), or (iii) of this Section 33, AADI shall be responsible for payment of Non-Approved Product under the terms of this Agreement. FRESENIUS KABI is not obliged to provide replacement for any defective Non-Approved Product. In the event FRESENIUS KABI agrees in writing to a replacement batch for Non-Approved Product (including and not limited on costs and associated timelines), Supplied Materials shall be provided free of charge by AADI.

2.11 To the extent a provision of the Agreement is not addressed under this Amendment, any obligations under such provision by FRESENIUS KABI and AADI that apply for Product shall apply also for [***] Product.

2.12 Exhibit B ("Delivery And Order Requirements") shall be deleted and replaced with Exhibit B attached to this Amendment.

2.13 Exhibit C shall be deleted and replaced with Exhibit C attached to this Amendment.

2.14 Exhibit G shall be deleted and replaced with Exhibit G attached to this Amendment.

3. INTEGRATION

Except for the sections of the Agreement specifically amended hereunder, all terms and conditions of the Agreement remain and shall remain in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

4. APPLICABLE LAW & JURISDICTION

This Amendment shall be governed by, and construed in accordance with, the laws which govern the Agreement, and the Parties submit to the jurisdiction and dispute resolution provisions as set forth in the Agreement.

[signature page follows immediately hereafter]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Exhibit 10.1

IN WITNESS WHEREOF, each Party is signing this Amendment on the date stated opposite that Party's signature.

AADi Bioscience, Inc.

By: /s/ David Lennon Date: April 1, 2024
Name: David Lennon
Title: Chief Executive Officer
AADi Bioscience, Inc.

By: /s/ Scott Giacobello Date: April 1, 2024
Name: Scott Giacobello
Title: Chief Financial Officer

Fresenius Kabi, LLC

By: /s/ Anthony Pavell Date: March 29, 2024
Name: Anthony Pavell
Title: Plant Manager

Fresenius Kabi, LLC

By: /s/ Saleem Farooqui Date: April 1, 2024
Name: Saleem Farooqui
Title:

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Exhibit 10.1

Exhibit B

DELIVERY AND ORDER REQUIREMENTS

1. Delivery Term (Incoterms® 2020)

   Product Delivery / [***] Product Delivery: FCA (Incoterms® 2020) FRESENIUS KABI facility in Grand Island, NY.

   All data loggers for the transport will be purchased by FRESENIUS KABI and will be invoiced at actual costs to Customer.

   FRESENIUS KABI shall provide the following documents upon delivery of Product or [***] Product:

   - Certificate of Analysis,
   - Certificate of Conformity, and
   - Packaging list.

   Warehouse addresses:

   TBD
   […]

2. With regard to packaging, labelling and export documentation requirements, the provisions of the Quality Agreement shall apply.

3. Order quantities and Batch

   Order quantity per order: [***] of Product or [***] Product

4. Order quantities per calendar month

   Maximum order quantity per calendar month: [***] (as described immediately above in paragraph 3). If in any calendar month FRESENIUS KABI cannot produce a batch pursuant to the Forecast due to unavailable manufacturing capacity, FRESENIUS KABI and AADI shall discuss in good faith potential manufacturing dates for such batch in the remaining part of term of the Agreement.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Exhibit 10.1

Exhibit C

PRICING AND PAYMENT

1. Price

The "PRICE TABLE" below identifies the price per unit of Product based on a batch size of [***] and [***], respectively.

PRICE TABLE – [***]:

[***]

PRICE TABLE – [***]:

[***]

Assumptions for Product and [***] Product prices include but are not limited to:

[***]

2. Invoice Currency

US Dollar ($)

3. Price Term

Price reviews shall be performed after the 1st of October of each given calendar year and shall be effective as of the 1st of January of each following year.

4. Payment details

Payment shall be made according to Section 12 of the Agreement. Payment shall be made to FRESENIUS KABI.

For non-ordered quantities of Product or [***] Product under the Forecast, AADI shall pay the price per unit of Product or [***] Product defined in this Exhibit C and as annually adjusted.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Exhibit 10.1

Exhibit G

FORECAST 2024 ("Product Manufacturing Timing Estimates" for 2024)

Batch #	Month/Year	Batch Size	Target Vials	Description
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

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, David J. Lennon, 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: May 8, 2024

By: /s/ *David J. Lennon, Ph.D.*

David J. Lennon, Ph.D.
Chief Executive Officer and President
(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: May 8, 2024

By: /s/ Scott Giacobello

Scott Giacobello
Chief Financial Officer
(Principal Financial 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 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I 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: May 8, 2024

By: /s/ David J. Lennon, Ph.D.

David J. Lennon, Ph.D.
Chief Executive Officer and President
(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 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I 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: May 8, 2024

By: /s/ Scott Giacobello

Scott Giacobello

Chief Financial Officer
(Principal Financial Officer)