
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 September 30, 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: 001-37746

APTEVO THERAPEUTICS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

81-1567056

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

2401 4th Avenue, Suite 1050

Seattle, Washington

98121

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (206) 838-0500

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

Title of Each Class

Common Stock, \$0.001 par value per share

Trading Symbols(s)

APVO

Name of Exchange on Which Registered

The Nasdaq Stock Market LLC
(The Nasdaq Capital Market)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 November 7, 2024, the number of shares of the registrant's common stock outstanding was 18,512,084.

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In this Quarterly Report on Form 10-Q, "we," "our," "us," "Aptevo," and "the Company" refer to Aptevo Therapeutics Inc. and, where appropriate, its consolidated subsidiaries.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts, unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,753	\$ 16,904
Prepaid expenses	1,635	1,473
Other current assets	624	689
Total current assets	10,012	19,066
Property and equipment, net	614	895
Operating lease right-of-use asset	4,520	4,881
Total assets	\$ 15,146	\$ 24,842
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 3,532	\$ 3,984
Accrued compensation	922	2,098
Other current liabilities	1,428	1,142
Total current liabilities	5,882	7,224
Other long-term liabilities	14	—
Operating lease liability	4,830	5,397
Total liabilities	10,726	12,621
Stockholders' equity:		
Preferred stock: \$0.001 par value; 15,000,000 shares authorized, zero shares issued or outstanding	—	—
Common stock: \$0.001 par value; 500,000,000 shares authorized; 17,050,536 and 442,458 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	82	61
Additional paid-in capital	245,603	235,607
Accumulated deficit	(241,265)	(223,447)
Total stockholders' equity	4,420	12,221
Total liabilities and stockholders' equity	\$ 15,146	\$ 24,842

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

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts, unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ (3,103)	\$ (3,887)	\$ (10,498)	\$ (13,516)
General and administrative	(2,110)	(2,674)	(7,722)	(8,978)
Loss from operations	(5,213)	(6,561)	(18,220)	(22,494)
Other income:				
Other income from continuing operations, net	112	227	402	390
Gain related to sale of non-financial asset	—	—	—	9,650
Net loss from continuing operations	\$ (5,101)	\$ (6,334)	\$ (17,818)	\$ (12,454)
Discontinued operations:				
Income from discontinued operations	\$ —	\$ —	\$ —	\$ 946
Net loss	<u>\$ (5,101)</u>	<u>\$ (6,334)</u>	<u>\$ (17,818)</u>	<u>\$ (11,508)</u>
Basic and diluted net loss per share from continuing operations:				
Basic	\$ (0.48)	\$ (22.16)	\$ (5.01)	\$ (60.84)
Diluted	<u>\$ (0.48)</u>	<u>\$ (22.16)</u>	<u>\$ (5.01)</u>	<u>\$ (60.84)</u>
Basic and diluted net loss per share:				
Basic	\$ (0.48)	\$ (22.16)	\$ (5.01)	\$ (56.22)
Diluted	<u>\$ (0.48)</u>	<u>\$ (22.16)</u>	<u>\$ (5.01)</u>	<u>\$ (56.22)</u>
Shares used in calculation:				
Basic	10,548,470	285,886	3,554,796	204,694
Diluted	<u>10,548,470</u>	<u>285,886</u>	<u>3,554,796</u>	<u>204,694</u>

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

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands, unaudited)

	For the Nine Months Ended September 30,	
	2024	2023
Operating Activities		
Net loss	\$ (17,818)	\$ (11,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,141	1,835
Depreciation and amortization	281	451
Non-cash interest expense and other	—	10
Changes in operating assets and liabilities:		
R royalty receivable	—	2,500
Prepaid expenses and other current assets	(96)	299
Operating lease right-of-use asset	361	311
Accounts payable, accrued compensation and other liabilities	(1,341)	129
Long-term operating lease liability	(554)	(504)
Net cash used in operating activities	<u>(18,026)</u>	<u>(6,477)</u>
Investing Activities		
Net cash from investing activities	—	—
Financing Activities		
Payments of long-term debt, including fees	—	(3,467)
Value of equity awards withheld for tax liability	(1)	(8)
Proceeds from issuance of common stock and pre-funded warrants	8,879	6,427
Payments in lieu of fractional shares	(3)	—
Net cash provided by financing activities	8,875	2,952
Decrease in cash and cash equivalents	(9,151)	(3,525)
Cash and cash equivalents at beginning of period	16,904	22,635
Cash and cash equivalents at end of period	<u>\$ 7,753</u>	<u>\$ 19,110</u>
Supplemental Cash Flow Information		
Warrant modification - incremental value	<u>\$ 472</u>	<u>\$ —</u>

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

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share amounts, unaudited)

	Common Stock		Additional Paid-In Capital		Accumulated Deficit		Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2023	442,458	\$ 61	\$ 235,607	\$ (223,447)	\$ 12,221		
Common stock issued upon vesting of restricted stock units	213	—	—	—	—	—	—
Issuances of common stock	231,130	5	(5)	—	—	—	—
Payment in lieu of fractional shares in connection with the 1-for-44 reverse stock split effected on March 5, 2024	(371)	—	(3)	—	(3)	—	719
Stock-based compensation	—	—	719	—	—	719	—
Net loss for the period	—	—	—	(6,834)	(6,834)	—	—
Balance at March 31, 2024	673,430	\$ 66	\$ 236,318	\$ (230,281)	\$ 6,103		
Common stock issued upon vesting of restricted stock units	2,257	—	—	—	—	—	—
Issuances of common stock	3,404,978	3	3,967	—	—	3,970	—
Stock-based compensation	—	—	273	—	—	273	—
Net loss for the period	—	—	—	(5,883)	(5,883)	—	—
Balance at June 30, 2024	4,080,665	\$ 69	\$ 240,558	\$ (236,164)	\$ 4,463		
Common stock issued upon vesting of restricted stock units	703	—	—	—	—	—	—
Issuances of common stock ⁽¹⁾	12,969,168	13	4,424	—	—	4,437	—
Warrant modification - incremental fair value	—	—	472	—	—	472	—
Stock-based compensation	—	—	149	—	—	149	—
Net loss for the period	—	—	—	(5,101)	(5,101)	—	—
Balance at September 30, 2024	17,050,536	\$ 82	\$ 245,603	\$ (241,265)	\$ 4,420		
	Common Stock		Additional Paid-In Capital		Accumulated Deficit		Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance at December 31, 2022	146,961	\$ 48	\$ 223,962	\$ (206,036)	\$ 17,974		
Common stock issued upon vesting of restricted stock units	961	—	(8)	—	—	(8)	—
Issuances of common stock	16,611	1	1,601	—	—	1,602	—
Stock-based compensation	—	—	915	—	—	915	—
Net income for the period	—	—	—	2,773	2,773	—	—
Balance at March 31, 2023	164,533	\$ 49	\$ 226,470	\$ (203,263)	\$ 23,256		
Common stock issued upon vesting of restricted stock units	90	—	(2)	—	—	(2)	—
Issuances of common stock	6,818	—	482	—	—	482	—
Stock-based compensation	—	—	465	—	—	465	—
Net loss for the period	—	—	—	(7,948)	(7,948)	—	—
Balance at June 30, 2023	171,441	\$ 49	\$ 227,415	\$ (211,211)	\$ 16,253		
Common stock issued upon vesting of restricted stock units	1,108	—	—	—	—	—	—
Issuances of common stock	50,489	2	1,197	—	—	1,199	—
Issuances of pre-funded warrants	105,725	5	3,140	—	—	3,145	—
Stock-based compensation	—	—	455	—	—	455	—
Net loss for the period	—	—	—	(6,334)	(6,334)	—	—
Balance at September 30, 2023	328,763	\$ 56	\$ 232,207	\$ (217,545)	\$ 14,718		

(1) Includes gross proceeds of \$5.8 million less issuance costs of \$1.3 million, which includes \$0.5 million warrant modification incremental fair value.

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

Aptevo Therapeutics Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. Nature of Business and Significant Accounting Policies

Organization and Liquidity

Aptevo Therapeutics Inc. (Aptevo, we, us, or the Company) is a clinical-stage, research and development biotechnology company focused on developing novel immuno-oncology candidates for the treatment of different forms of cancer. We have developed two versatile and enabling platform technologies for rational design of precision immune modulatory drugs. Our clinical candidates, mipletamig (formerly APVO436) and ALG-APV-527, and preclinical candidates, APVO603 and APVO711, were developed using our ADAPTIR™ modular protein technology platform. Our preclinical candidate APVO442 was developed using our ADAPTIR-FLEX™ modular protein technology platform.

We are currently trading on the Nasdaq Capital Market under the symbol "APVO."

The accompanying financial statements have been prepared on a basis that assumes we will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of the uncertainty of our ability to continue as a going concern, nor do they include adjustments to reflect the possible future effects of the recoverability and classification of recorded asset amounts and classifications of liabilities that might be necessary should the Company be unable to continue as a going concern. For the nine months ended September 30, 2024, we had a net loss of \$17.8 million. We had an accumulated deficit of \$241.3 million as of September 30, 2024. For the nine months ended September 30, 2024, net cash used in our operating activities was \$18.0 million. We have suffered recurring losses from operations and negative cash flows from operating activities. When considered in aggregate, these factors raise substantial doubt about our ability to continue as a going concern for the one-year period from the date of issuance of these financial statements. We will need to raise additional funds to support our operating and capital needs in addition to our existing cash resources, cash to be generated from future milestones related to IXINITY sales and regulatory approvals achieved by Medexus Pharmaceuticals ("Medexus"), and exercise of common warrants. We may choose to raise additional funds to support our operating and capital needs in the future.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to: (a) changes we may make to the business that affect ongoing operating expenses; (b) changes we may make in our business strategy; (c) changes we may make in our research and development spending plans; (d) whether and to what extent potential milestones are received from Medexus with respect to IXINITY; (e) macroeconomic conditions such as rising interest rates, inflation and costs; and (f) other items affecting our forecasted level of expenditures and use of cash resources. We may attempt to obtain other public or private financing, collaborative or licensing arrangements with strategic partners, or through credit lines or other debt financing sources to increase the funds available to fund operations. However, we may not be able to secure such funding in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences, and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration, licensing, or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back, or eliminate some of our research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development goals may be adversely affected. Given the continuing global economic and geopolitical climate, including rising interest rates and stock market volatility, we may experience delays or difficulties in the financing environment and raising capital due to economic uncertainty.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). These unaudited condensed consolidated financial statements include all adjustments, which include normal recurring adjustments, necessary for the fair presentation of the Company's financial position. These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2023, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates and changes in these estimates are recorded when known.

The unaudited condensed consolidated financial statements include the accounts of the Company and our wholly owned subsidiary, Aptevo Research and Development LLC ("Aptevo R&D"). All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures of contingent liabilities in the unaudited condensed financial statements and accompanying notes. Estimates are used for, but not limited to, clinical accruals, useful lives of equipment, commitments and contingencies, stock-based compensation, and incremental borrowing rate (IBR) used for our lease. Given the global economic and geopolitical climate, these estimates are becoming more challenging, and actual results could differ materially from those estimates.

Significant Accounting Policies

Gain Related to Sale of Nonfinancial Asset to XOMA (US) LLC

On March 29, 2023, we entered into and closed a payment interest purchase agreement (the "Purchase Agreement") with XOMA (US) LLC ("XOMA") pursuant to which we sold to XOMA our right, title and interest in all of the deferred payments and a portion of the milestone payments from Medexus pursuant to our LLC Purchase Agreement with Medexus, dated February 28, 2020 (the "LLC Purchase Agreement"). Under the terms of the Purchase Agreement, we received \$9.6 million at closing (the "Closing Payment") and an additional post-closing payment of \$0.05 million.

We accounted for the \$9.6 million Closing Payment and the \$0.05 million post-closing payment from XOMA as other income in accordance with Accounting Standards Codification ("ASC") 610-20 *Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets* in the first quarter of 2023. Contractual rights sold to XOMA represent an intangible asset under ASC 610-20 *Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets* for which XOMA bears all benefit and Aptevio has no obligations going forward. The Company will continue to account for its portion of future milestones under our LLC Purchase Agreement with Medexus as contingent consideration under ASC 450-30 *Gain Contingencies* and will record income when proceeds are received.

Other Significant Accounting Policies

Our other significant accounting policies were reported in our Annual Report on Form 10-K for the year ended December 31, 2023 that was filed with the Securities and Exchange Commission (the "SEC") on March 5, 2024. Our other significant accounting policies have not changed materially from the policies previously reported.

Note 2. Discontinued Operations

The accompanying unaudited condensed consolidated financial statements include discontinued operations from the sale of business products and segments.

The following table represents the components attributable to income from discontinued operations in the unaudited condensed consolidated statements of operations (in thousands):

	Nine Months Ended September 30, 2023
Deferred payment from Medexus	523
Gain on contingent consideration from release of escrow related to sale of Aptevio BioTherapeutics	163
Gain on contingent consideration from Kamada	260
Income from discontinued operations	<hr/> \$ 946

For the nine months ended September 30, 2024, we did not record income from discontinued operations. For the nine months ended September 30, 2023, we collected \$0.5 million in deferred payments from Medexus related to IXINITY sales and \$0.2 million related to funds released from escrow from the sale of Aptevio BioTherapeutics in 2020. Additionally, we received \$0.3 million related to the sale of hyperimmune business to Saol (later acquired by Kamada, Ltd.) as a result of the collection of certain accounts receivable.

Note 3. XOMA Transaction

On March 29, 2023, we entered into and closed a Purchase Agreement with XOMA pursuant to which we sold to XOMA our right, title and interest in and to all of the deferred payments and a portion of the milestone payments from Medexus under our LLC Purchase Agreement. Under the terms of our Purchase Agreement with XOMA, we received \$9.6 million at closing and an additional post-closing payment of \$0.05 million. In exchange for the Closing Payment, we sold to XOMA our right, title and interest to the following payments under the LLC Purchase Agreement: (i) 100% of the Company's entitlement to receive the deferred payments that may become due and payable following March 29, 2023 (including, for avoidance of doubt, any and all payments earned during Q1 2023), (ii) 25% of the Company's entitlement to receive the Canadian approval milestone payment; and (iii) 50% of the Company's entitlement to receive the European approval milestone payments and net sales milestone payment.

We accounted for the \$9.6 million Closing Payment and the \$0.05 million post-closing payment from XOMA as other income in accordance with ASC 610-20 *Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets* in the first quarter of 2023. Contractual rights sold to XOMA represent an intangible asset under ASC 610-20 *Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets* for which XOMA bears all benefit and Apteko has no obligations going forward. The Company will continue to account for its portion of future milestones under our LLC Purchase Agreement with Medexus as contingent consideration under ASC 450-30 *Gain Contingencies* and will record income when proceeds are received.

Note 4. Collaboration Agreements

Alligator Bioscience AB

On July 20, 2017, our wholly owned subsidiary, Apteko R&D, entered into a collaboration and option agreement (the "Collaboration Agreement") with Alligator Bioscience AB ("Alligator"), pursuant to which Apteko and Alligator have been collaboratively developing ALG.APV-527, a first-in-class bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a costimulatory receptor found on activated T cells, and 5T4, a tumor antigen widely overexpressed in a number of different types of cancer.

We assessed the arrangement in accordance with ASC 606 and concluded that the contract counterparty, Alligator, is not a customer. As such the arrangement is not in the scope of ASC 606 and is instead treated as a collaborative agreement under ASC 808 – *Collaborative Arrangements* ("ASC 808"). In accordance with ASC 808, we concluded that because the Collaboration Agreement is a cost sharing agreement, there is no revenue.

For the nine months ended September 30, 2024 and 2023, we recorded approximately \$1.9 million and \$2.0 million, which represent our 50% cost share, in our research and development expense related to the Collaboration Agreement, respectively.

Note 5. Fair Value Measurements

The Company's estimates of fair value for financial assets and financial liabilities are based on the framework established in the fair value accounting guidance. The framework is based on the inputs used in valuation, it gives the highest priority to quoted prices in active markets and requires that observable inputs be used in the valuations when available. The disclosure of fair value estimates in the fair value accounting guidance hierarchy is based on whether the significant inputs into the valuation are observable. In determining the level of the hierarchy in which the estimate is disclosed, the highest priority is given to unadjusted quoted prices in active markets and the lowest priority to unobservable inputs that reflect the Company's significant market assumptions. The level in the fair value hierarchy within which the fair value measurement is reported is based on the lowest level input that is significant to the measurement in its entirety. The three levels of the hierarchy are as follows:

Level 1— Quoted prices in active markets for identical assets and liabilities;

Level 2— Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3— Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

At September 30, 2024 and December 31, 2023, we had \$5.8 million and \$13.2 million in Level 1 money market funds, respectively. The carrying amounts of our money market funds approximate their fair value. At September 30, 2024 and December 31, 2023, we did not have any Level 2 or Level 3 assets.

Note 6. Cash and Cash Equivalents

The Company's cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and include time deposits and investments in money market funds.

The following table shows our cash and cash equivalents as of September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
(in thousands)		
Cash	\$ 1,966	\$ 3,733
Cash equivalents	5,787	13,171
Total cash and cash equivalents	\$ 7,753	\$ 16,904

Note 7. Leases

Office Space Lease - Operating

We have an operating lease related to our office and laboratory space in Seattle, Washington with a term through April 2030 and two options to extend the lease term, each by five years. As of September 30, 2024, we are not reasonably certain to exercise the two options to extend the lease term and our lease liability is recorded through April 30, 2030.

For the three and nine months ended September 30, 2024, we recorded \$0.2 million and \$0.6 million, respectively, related to variable lease expense. For the three and nine months ended September 30, 2023, we recorded \$0.3 million and \$0.6 million, respectively, related to variable lease expense.

Components of lease expense:

(in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease cost	\$ 297	\$ 297	\$ 890	\$ 890
Total lease cost	<u>\$ 297</u>	<u>\$ 297</u>	<u>\$ 890</u>	<u>\$ 890</u>

Right of use assets acquired under operating leases:

(in thousands)	As of September 30,		As of December 31,	
	2024	2023	2023	2023
Seattle office lease, including amendment	\$ 4,520	\$ 4,881		
Total operating leases	<u>\$ 4,520</u>	<u>\$ 4,881</u>		

Lease payments:

(in thousands)	For the Nine Months Ended September 30,		
	2024	2023	2023
For operating leases	\$ 1,032	\$ 803	

As of September 30, 2024, the long-term and current portion of the lease liabilities was \$4.8 million and \$0.7 million, respectively. As of September 30, 2023, the long-term and current portion of the lease liabilities was \$5.6 million and \$0.7 million, respectively.

As of September 30, 2024, the weighted-average remaining lease term and weighted-average discount rate for operating leases was 5.58 years and 12.03%.

Note 8. Reverse Stock Split

On February 5, 2024, we held a Special Meeting of the Stockholders (the "Special Meeting") at which our stockholders approved a series of alternate amendments to the Amended and Restated Certificate of Incorporation to effect, at the option of our Board of Directors (the "Board"), a reverse split of Apteko's common stock at a ratio ranging from 1-for-15 to 1-for-44, inclusive, with the effectiveness of one of such amendments and the abandonment of the other amendments, or the abandonment of all amendments, to be determined by the Board in its sole discretion following the Special Meeting. The specific 1-for-44 reverse split ratio was subsequently approved by the Board on February 27, 2024. On March 5, 2024, the Company filed a Certificate of Amendment of Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a 1-for-44 reverse stock split of the Company's outstanding common stock (the "Reverse Stock Split"). The Reverse Stock Split became effective on March 5, 2024 at 5:01 p.m. Eastern Time, and our common stock began trading on the Nasdaq Capital Market, on a split-adjusted basis, at market open on March 6, 2024.

No fractional shares were issued as a result of the Reverse Stock Split. Stockholders of record who would otherwise be entitled to receive a fractional share received a cash payment in lieu thereof.

We have adjusted all common stock and stock equivalent figures retroactively in this Form 10-Q for all periods presented to reflect the Reverse Stock Split.

Note 9. Net Income (Loss) per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of common share equivalents outstanding for the period using the as-if converted method. Shares of the Company's common stock underlying pre-funded warrants are included in the calculation of basic and diluted earnings per share because there is little to no consideration required for delivery of shares. For the purpose of this calculation, warrants, stock options and restricted stock units ("RSUs") are only included in the calculation of diluted net income (loss) per share when their effect is dilutive.

We utilize the control number concept in the computation of diluted earnings per share to determine whether potential common stock instruments are dilutive. The control number used is income (loss) from continuing operations or income (loss) from discontinued operations. The control number concept requires that the same number of potentially dilutive securities applied in computing diluted earnings per share from continuing operations be applied to all other categories of income or loss, regardless of their anti-dilutive effect on such categories.

Common stock equivalents include warrants, stock options and unvested RSUs.

The following table presents the computation of basic and diluted net loss per share (in thousands, except share and per share amounts):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss from continuing operations	\$ (5,101)	\$ (6,334)	\$ (17,818)	\$ (12,454)
Income from discontinued operations	—	—	—	946
Net loss	<u>\$ (5,101)</u>	<u>\$ (6,334)</u>	<u>\$ (17,818)</u>	<u>\$ (11,508)</u>
Basic and diluted net loss per share from continuing operations:				
Basic	\$ (0.48)	\$ (22.16)	\$ (5.01)	\$ (60.84)
Diluted	\$ (0.48)	\$ (22.16)	\$ (5.01)	\$ (60.84)
Basic and diluted net income per share from discontinued operations:				
Basic	\$ —	\$ —	\$ —	\$ 4.62
Diluted	\$ —	\$ —	\$ —	\$ 4.62
Basic and diluted net loss per share:				
Basic	<u>\$ (0.48)</u>	<u>\$ (22.16)</u>	<u>\$ (5.01)</u>	<u>\$ (56.22)</u>
Diluted	<u>\$ (0.48)</u>	<u>\$ (22.16)</u>	<u>\$ (5.01)</u>	<u>\$ (56.22)</u>
Shares used in calculation:				
Basic	10,548,470	285,886	3,554,796	204,694
Diluted	10,548,470	285,886	3,554,796	204,694

The following table represents all potentially dilutive shares:

	As of September 30,	
	2024	2023
Warrants	36,350,685	401,603
Outstanding options to purchase common stock	9,624	10,595
Unvested RSUs	69,458	6,489

We use the treasury stock method when determining dilutive shares. For the three and nine months ended September 30, 2024 and 2023, the Company was in a net loss position, therefore the share number used to calculate diluted earnings per share is the same as the basic earnings per share.

Note 10. Equity

August 2023 Public Offering

On August 4, 2023, we completed a public offering of common stock and warrants, which included the following:

- 50,488 shares of common stock at a price of \$27.28 per share.
- Pre-funded warrants to purchase up to 132,793 shares of common stock at a price of \$27.28 per share with an exercise price of \$0.001 per share. As of September 30, 2024, all pre-funded warrants have been exercised.
- Series A and Series B common warrants to purchase up to an aggregate of 366,562 shares of common stock at an exercise price of \$27.28 per share.

We received net proceeds of \$4.3 million, net of transaction costs, as a result of this offering. In the fourth quarter of 2023, an aggregate of 322,691 Series A and Series B common warrants were exercised as part of our November 2023 warrant inducement agreement with certain holders of our common warrants. The Series A and Series B common warrants are exercisable immediately following the date of issuance and will expire on August 4, 2028 and February 4, 2025, respectively. In connection with a registered direct offering of the Company that closed on July 1, 2024 (the "July Registered Direct Offering"), the Company amended certain existing common warrants held by certain stockholders who participated in the July Registered Direct Offering that were issued in our August 2023 public offering, such that these common warrants will have a reduced exercise price equal to \$0.515 per share and include the same exercise price adjustment terms as the common warrants issued in the July Registered Direct Offering. As of September 30, 2024, we have 1,316 Series A and 1,316 Series B common warrants outstanding to purchase shares of our common stock at an exercise price of \$27.28 per share and 41,239 Series A common warrants outstanding with an amended exercise price of \$0.515 per share that were issued in connection with the August 2023 public offering.

If such warrants are exercised at their current exercise price, we will receive up to an additional \$0.1 million in gross proceeds in connection with the warrants issued as part of the August 2023 public offering.

November 2023 Warrant Inducement

On November 9, 2023, we entered into a warrant inducement agreement (the "Inducement Agreement") with certain holders of our Series A and Series B common warrants issued in connection with our August 2023 public offering to exercise for cash 140,726 Series A and 181,965 Series B common warrants at a reduced exercise price of \$10.25. We received \$3.3 million in gross proceeds from the exercise of these warrants and issued an aggregate of 645,382 new Series A and new Series B warrants as follows:

- 281,452 Series A common warrants to purchase an aggregate of up to 281,452 shares of common stock at \$10.25 per share, of which 140,726 Series A-1 common warrants were immediately exercisable and 140,726 Series A-2 common warrants were exercisable at any time on or after February 5, 2024. The Series A-1 and Series A-2 common warrants have terms of four years and eight months, and five years, respectively.
- 363,930 Series B common warrants to purchase an aggregate of up to 363,930 shares of common stock at \$10.25 per share, of which 181,965 Series B-1 common warrants were immediately exercisable and 181,695 Series B-2 common warrants were exercisable at any time on or after February 5, 2024. The Series B-1 and Series B-2 common warrants have terms of fourteen months and twenty-four months, respectively.

In connection with the July Registered Direct Offering and a registered direct offering of the Company that closed on September 18, 2024 (the "September Registered Direct Offering"), the Company amended certain existing common warrants held by certain stockholders who participated in the registered direct offerings that were issued in our November 2023 warrant inducement, such that these common warrants will have a reduced exercise price equal to \$0.515 per share and \$0.33 per share, respectively, and include the same exercise price adjustment terms as the common warrants issued in the July Registered Direct Offering and September Registered Direct Offering. As of September 30, 2024, we have 17,524 Series A and 17,524 Series B common warrants outstanding with an exercise price of \$10.25 per share, 82,478 Series A and 164,956 Series B common warrants with an amended exercise price of \$0.515 per share and 181,450 Series A common warrants and 181,450 Series B common warrants with an amended exercise price of \$0.33 per share that were issued in connection with the Inducement Agreement.

If such warrants are exercised at their current exercise price, we will receive up to an additional \$0.6 million in gross proceeds in connection with the warrants issued in connection with the Inducement Agreement.

April 2024 Public Offering

On April 15, 2024, we completed a public offering of common stock and warrants, in which we received net proceeds of \$4.0 million, net of transaction costs, which included the following:

- 926,666 shares of common stock and accompanying common warrants to purchase up to 1,853,332 shares of common stock at a public offering price of \$1.35 per share; and
- Pre-funded warrants to purchase up to 2,473,334 shares of common stock and accompanying common warrants to purchase up to 4,946,668 shares of common stock at a combined public offering price of \$1.3499 per pre-funded warrant, which is equal to the public offering price per share of common stock less the \$0.0001 per share exercise price of each such pre-funded warrant. As of September 30, 2024, all pre-funded warrants have been exercised.

The common warrants are exercisable immediately following the date of issuance and will expire in April 2029. On July 1, 2024, and September 18, 2024, in connection with the July Registered Direct Offering and September Registered Direct Offering, respectively, the Company amended certain existing common warrants held by certain stockholders who participated in the registered direct offerings that were issued in our April 2024 public offering, such that these common warrants will have a reduced exercise price equal to \$0.515 per share and \$0.33 per share, respectively, and include the same exercise price adjustment terms as the common warrants issued in the July Registered Direct Offering and the September Registered Direct Offering. As of September 30, 2024, we have 133,332 common

warrants outstanding with an exercise price of \$1.35 per share, 2,222,222 common warrants with an amended exercise price of \$0.515 per share and 4,444,446 common warrants with an amended exercise price of \$0.33 per share that were issued in connection with the April 2024 public offering.

If such warrants are exercised at their current exercise price, we will receive up to an additional \$2.8 million in proceeds in connection with the warrants issued in connection with the April 2024 public offering.

July 2024 Registered Direct Offering

On July 1, 2024, we completed the July Registered Direct Offering with certain holders of our outstanding common warrants issued in connection with our previous offerings. Pursuant to the July Registered Direct Offering, certain holders agreed to amend the exercise price of 7,318,241 existing warrants to a reduced exercise price of \$0.515 per share. We received \$2.7 million in gross proceeds less total issuance costs of \$0.8 million. Issuance costs include banker and legal fees of \$0.4 million and non-cash warrant modification costs of \$0.4 million. The Company recognized the \$0.4 modification date incremental value of the modified warrants as compared to the original warrants as a non-cash issuance cost of the July Registered Direct Offering. Additionally, pursuant to the July Registered Direct Offering, we issued the following:

- 3,621,460 shares of common stock and accompanying common warrants to purchase up to 7,242,920 shares of common stock at an offering price of \$0.515 per share; and
- Pre-funded warrants to purchase up to 1,718,346 shares of common stock and accompanying common warrants to purchase up to 3,436,692 shares of common stock at a combined offering price of \$0.5149 per pre-funded warrant, which is equal to the offering price of per share of common stock less the \$0.0001 per share exercise price of each such pre-funded warrant. As of September 30, 2024, all pre-funded warrants have been exercised.

The common warrants became exercisable immediately following stockholder approval on August 6, 2024, and will expire in August 2029. In connection with the July Registered Direct Offering, the Company amended certain existing common warrants that were previously issued to certain investors such that these common warrants will have a reduced exercise price equal to \$0.515 per share and include the same exercise price adjustments as the common warrants issued in the July Registered Direct Offering. These amended warrants became exercisable immediately following stockholder approval on August 6, 2024. On September 18, 2024, in connection with the September Registered Direct Offering, the Company amended certain existing common warrants held by certain stockholders who participated in the September Registered Direct Offering that were issued in the July Registered Direct Offering, such that these common warrants will have a reduced exercise price equal to \$0.33 per share, and include the same exercise price adjustments as the common warrants issued in the September Registered Direct Offering. As of September 30, 2024, we have 3,664,184 common warrants outstanding at an exercise price of \$0.515 per share and 7,015,428 common warrants outstanding at an amended exercise price of \$0.33 per share that were issued in connection with the July Registered Direct Offering.

If such warrants are exercised at their current exercise price, we will receive up to an additional \$4.2 million in proceeds in connection with the warrants issued in connection with the July Registered Direct Offering.

September 2024 Registered Direct Offering

On September 18, 2024, we completed the September Registered Direct Offering with certain holders of our outstanding common warrants issued in connection with our previous offerings. Pursuant to the September Registered Direct Offering, certain holders agreed to amend the exercise price of 11,822,774 existing warrants to a reduced exercise price of \$0.33 per share. We received \$3.0 million in gross proceeds less total issuance costs of \$0.5 million. Issuance costs include banker and legal fees of \$0.4 million and non-cash warrant modification costs of \$0.1 million. The Company recognized the \$0.1 million modification date incremental value of the modified warrants as compared to the original warrants as a non-cash issuance cost of the September Registered Direct Offering. Additionally, pursuant to the September Registered Direct Offering, we issued the following:

- 4,020,000 shares of common stock and accompanying common warrants to purchase up to 8,040,000 shares of common stock at an offering price of \$0.33 per share; and
- Pre-funded warrants to purchase up to 5,070,910 shares of common stock and accompanying common warrants to purchase up to 10,141,820 shares of common stock at a combined offering price of \$0.3299 per pre-funded warrant, which is equal to the offering price of per share of common stock less the \$0.0001 per share exercise price of each such pre-funded warrant. As of September 30, 2024, 3,609,362 pre-funded warrants have been exercised and 1,461,548 pre-funded warrants remain outstanding.

The common warrants became exercisable immediately following the date of stockholder approval on October 25, 2024, and will expire in October 2029. In connection with the September Registered Direct Offering, the Company amended certain existing common warrants that were previously issued to certain investors such that these common warrants will have a reduced exercise price equal to \$0.33 per share and include the same exercise price adjustments as the common warrants issued in the September Registered Direct Offering. These amended warrants became exercisable immediately following stockholder approval on October 25, 2024. As of September 30, 2024, we have issued and outstanding common warrants to purchase 18,181,820 shares of our common stock at an exercise price of \$0.33 per share in connection with the September Registered Direct Offering, which became exercisable immediately following stockholder approval on October 25, 2024.

If such warrants are exercised at their current exercise price, we will receive up to an additional \$6.0 million in proceeds in connection with the warrants issued in connection with the September Registered Direct Offering.

The following is a summary of common warrant activity for the nine months ended September 30, 2024:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Term
Outstanding at December 31, 2023	697,220	\$ 20.36	2.99
Issued	35,661,432	0.58	4.85
Exercised	—	—	—
Expired	(7,967)	800.80	—
Outstanding at September 30, 2024 ⁽¹⁾	36,350,685	\$ 0.38	4.80
Exercisable at September 30, 2024	<u>18,168,865</u>	<u>\$ 0.54</u>	<u>4.61</u>

(1) The weighted average exercise price of outstanding common warrants includes adjustments to the exercise price of existing common warrants during our July and September 2024 direct offerings.

Aptevo uses Black-Scholes valuation model for estimating the fair value of the common warrants included in public and direct offerings. Set forth below are the assumptions used in valuing the common warrants issued:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Expected volatility	113.24%	103.57%	112.16%	103.57%
Risk-free interest rate	5.27%	5.33%	5.23%	4.18%
Expected average life of warrants	5 years	5 years	3.25 years	3.25 years

Equity Distribution Agreement

The Company previously entered into an Equity Distribution Agreement with Piper Sandler (the "Equity Distribution Agreement") under which we could issue and sell through Piper Sandler shares of our common stock pursuant to a Registration Statement on Form S-3 (the "Shelf Registration Statement") which we filed on December 14, 2020, and expired in December 2023. In the nine months ended September 30, 2023, the Company issued 16,611 shares of common stock at an average price of \$99.43 under the Equity Distribution Agreement. We received \$1.6 million in proceeds from the issuance of these shares.

Lincoln Park Purchase Agreement

On February 16, 2022, we entered into a Purchase Agreement ("2022 Purchase Agreement") and a Registration Rights Agreement with Lincoln Park (the "Registration Rights Agreement") to purchase up to \$35.0 million of our common stock over a 36-month period, for which we issued 2,256 shares of our common stock to Lincoln Park for no cash consideration as an initial fee for its commitment to purchase shares of our common stock under the 2022 Purchase Agreement. For the nine months ended September 30, 2024, we did not issue shares of our common stock and for the nine months ended September 30, 2023, we issued 6,818 shares of our common stock to Lincoln Park under the 2022 Purchase Agreement and we received \$0.5 million in proceeds from issuance of these shares. Our Shelf Registration Statement on Form S-3 expired on December 18, 2023, without which we cannot issue shares pursuant to the 2022 Purchase Agreement.

Rights Plan

On November 8, 2020, our Board approved and adopted a Rights Agreement (the "Rights Agreement"), dated as of November 8, 2020, by and between the Company and Broadridge Corporate Issuer Solutions, Inc., as rights agent, pursuant to which the Board declared a dividend of one preferred share purchase right (each, a "Right") for each outstanding share of the Company's common stock held by stockholders as of the close of business on November 23, 2020. One Right also will be issued together with each common share issued by the Company after November 23, 2020, but before the Distribution Date (as defined in the Rights Agreement) (or the earlier

redemption or expiration of the Rights) and, in certain circumstances, after the Distribution Date. When exercisable, each Right initially would represent the right to purchase from the Company one one-thousandth of a share of a newly-designated series of preferred stock, Series A Junior Participating Preferred Stock, par value \$0.001 per share, of the Company. Subject to various exceptions, the Rights become exercisable in the event any person (excluding certain exempted or grandfathered persons) becomes the beneficial owner of ten percent (10%) or more of the Company's common stock without the approval of the Board. On November 1, 2024, we entered into amendment No. 4 to the Rights Agreement and extended the expiration of such agreement to October 31, 2025 and changed the exercise price to \$70 per one one-thousandth of a Series A Junior Participating Preferred Share (as defined in the Rights Agreement), subject to adjustment.

2018 Stock Incentive Plan

On June 1, 2018, at the 2018 annual meeting of the stockholders, the Company's stockholders approved a new 2018 Stock Incentive Plan (the "2018 SIP"), which replaced the Restated 2016 Plan (the "2016 SIP") on a go-forward basis. All stock options, RSUs or other equity awards granted subsequent to June 1, 2018 have been and will be issued out of the 2018 SIP, which has 0.1 million shares of Apteko common stock authorized for issuance. The 2018 SIP became effective immediately upon stockholder approval at the 2018 annual meeting of the stockholders. Any shares subject to outstanding stock awards granted under the 2016 SIP that (a) expire or terminate for any reason prior to exercise or settlement; (b) are forfeited because of the failure to meet a contingency or condition required to vest such shares or otherwise return to the Company; or (c) otherwise would have returned to the 2016 SIP for future grant pursuant to the terms of the 2016 SIP (such shares, the "Returning Shares") will immediately be added to the share reserve under the 2018 SIP as and when such shares become Returning Shares, up to a maximum of 0.1 million shares.

On June 7, 2022, at the 2022 annual meeting of the stockholders, our stockholders approved the Amended and Restated 2018 SIP (the "Amended 2018 SIP") to increase the number of shares authorized for issuance under the 2018 SIP by 11,363 shares of common stock (adjusted for 1-for-44 reverse stock split effective as of March 5, 2024).

On June 7, 2024, at the 2024 annual meeting of the stockholders, our stockholders approved the Second Amended and Restated 2018 SIP (the "Second Amended 2018 SIP") to increase the number of shares authorized for issuance under the Amended 2018 SIP by 165,000 shares of common stock. As of September 30, 2024, there are 0.1 million shares available to be granted under the Second Amended 2018 SIP.

Stock options and RSUs under the Second Amended 2018 SIP generally vest pro rata over a one-year or three-year period. Stock options terminate ten years from the grant date, though the specific terms of each grant are determined individually. The Company's executive officers, members of our Board, and certain other employees and consultants may be awarded options and/or RSUs with different vesting criteria, and awards granted to non-employee directors will vest over a one-year period. Option exercise and RSU grant prices for new awards granted by the Company equal the closing price of the Company's common stock on the Nasdaq Capital Market on the date of grant.

Stock-Based Compensation Expense

Stock-based compensation expense includes amortization of stock options and RSUs granted to employees and non-employees and has been reported in our unaudited condensed consolidated statements of operations as follows:

(in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 54	\$ 143	\$ 345	\$ 565
General and administrative	95	312	796	1,270
Total stock-based compensation expense	\$ 149	\$ 455	\$ 1,141	\$ 1,835

The Company accounts for stock-based compensation by measuring the cost of employee services received in exchange for all equity awards granted based on the fair value of the award as of the grant date. The Company recognizes the compensation expense over the vesting period. All assumptions used to calculate the grant date fair value of non-employee equity awards are generally consistent with the assumptions used for equity awards granted to employees. In the event the Company terminates any of its consulting agreements, the unvested equity underlying the agreements would also be forfeited. The stock compensation is lower in the current period mainly due to a decrease in our stock price.

Stock Options

Aptevo utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. Set forth below are the assumptions used in valuing the stock options granted:

	Nine Months Ended September 30, 2023
Expected dividend yield	—
Expected volatility	103.63%
Risk-free interest rate	4.18%
Expected average life of options	5 years

The Company did not grant stock options for the three and nine months ended September 30, 2024, or for the three months ended September 30, 2023. For the nine months ended September 30, 2023, management has applied an estimated forfeiture rate of 30%.

The following is a summary of option activity for the nine months ended September 30, 2024:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Term
Balance at December 31, 2023	9,946	\$ 563.19	7.38
Granted	—	—	—
Exercised	—	—	—
Forfeited	(322)	620.32	—
Outstanding at September 30, 2024	<u>9,624</u>	<u>\$ 557.31</u>	<u>6.80</u>
Exercisable September 30, 2024	<u>7,262</u>	<u>\$ 692.42</u>	<u>6.36</u>
Vested and expected to vest at September 30, 2024	<u>9,210</u>	<u>\$ 577.17</u>	<u>6.74</u>

As of September 30, 2024, we had \$0.2 million of unrecognized compensation expense related to options expected to vest over a weighted-average remaining vesting period of 0.8 years. The weighted-average grant date fair value per share of options granted during the nine months ended September 30, 2023, was \$73.83. The total fair value of stock options vested for the nine months ended September 30, 2024 and 2023 was \$1.1 million and \$1.2 million, respectively.

The aggregate intrinsic value is the total pretax intrinsic value (the difference between the closing stock price of Aptevo's common stock on the last trading day of September 30, 2024 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all the option holders exercised their options on the last trading day of the quarter.

Restricted Stock Units

The following is a summary of RSU activity for the nine months ended September 30, 2024:

	Number of Units	Weighted Average Fair Value per Unit
Balance at December 31, 2023	6,342	\$ 205.08
Granted	66,632	0.74
Vested	(3,281)	264.71
Forfeited	(235)	76.28
Outstanding and expected to vest at September 30, 2024	<u>69,458</u>	<u>\$ 6.68</u>

As of September 30, 2024, there was \$0.3 million unrecognized stock-based compensation expense related to unvested RSUs expected to vest over the weighted-average period of 1.2 years.

The fair value of each RSU has been determined to be the closing trading price of the Company's common stock on the date of grant as quoted on the Nasdaq Capital Market.

Note 11. Subsequent Events

On October 21 and October 23, 2024, holders of our September 2024 pre-funded warrants provided notice to exercise 1,190,587 and 270,961 pre-funded warrants, respectively, and 1,461,548 total shares of common stock were then issued. As of November 7, 2024, we have no remaining pre-funded warrants outstanding and 18,512,084 shares of common stock issued and outstanding.

On October 25, 2024, the Company held a Special Meeting of Stockholders (the "Special Meeting"), at which the Company's stockholders:

- 1.Approved, in accordance with Nasdaq Listing Rule 5635(d), the issuance of more than 19.99% of our outstanding common stock, par value \$0.001 per share, issuable upon the exercise of common warrants issued pursuant to the September Registered Direct Offering, which includes an exercise price adjustment provision in the event of an issuance of common stock or common stock equivalent, an option to purchase common stock or common stock equivalent, change in price of common stock or common stock equivalent or other such event as described in the common warrants and to approve the amendment of certain existing common warrants to include the same exercise price adjustment provisions and the repricing of such existing warrants pursuant to the September Registered Direct Offering ("Proposal 1");
- 2.Approved an amendment to our Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our Common Stock at a ratio in the range of 1-for-5 to 1-for-37, with such ratio to be determined in the discretion of our Board and with such reverse stock split to be effected at such time and date, if at all, as determined by our Board in its sole discretion ("Proposal 2"); and
- 3.Approved an authorization to adjourn the Special Meeting, if necessary or appropriate, to solicit additional proxies if there are not sufficient votes in favor of Proposal 1 or Proposal 2 ("Proposal 3").

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

This Quarterly Report on Form 10-Q includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements in this Quarterly Report on Form 10-Q other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, the achievement of milestones and receipt of future payments, projected costs, prospects, plans, intentions, expectations, clinical trial results, compliance with listing requirements, future macroeconomic conditions and objectives could be forward-looking statements. The words "anticipates," "believes," "could," "designed," "estimates," "expects," "goal," "intends," "may," "plans," "projects," "should," "will," "would" and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

We have based these forward-looking statements largely on our current assumptions, expectations, projections, intentions, objectives and/or beliefs about future events or occurrences and these forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to, those described in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. The timing of certain events and circumstances and known and unknown risks and uncertainties could cause actual results to differ materially from those anticipated or implied in the forward-looking statements that we make. Therefore, you should not place undue reliance on our forward-looking statements. Our forward-looking statements in this Quarterly Report on Form 10-Q are based on current information and we do not assume any obligation to update any forward-looking statements except as required by the federal securities laws.

You should read the following Management's Discussion and Analysis of Financial Condition and Results of Operations (this MD&A) together with the unaudited condensed consolidated financial statements and the related notes thereto included in this Quarterly Report on Form 10-Q. This MD&A contains forward-looking statements that are subject to risks and uncertainties, such as those set forth in the sections of this Quarterly Report on Form 10-Q, "Risk Factors" and elsewhere. As a result, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical-stage, research and development biotechnology company focused on developing novel immunotherapy candidates for the treatment of different forms of cancer. We have developed two versatile and enabling platform technologies for rational design of precision immune modulatory drugs and have two clinical candidates and three preclinical candidates currently in development. Clinical candidate mipletamig (formerly APVO436) is a CD3xCD123 T-cell engager currently being clinically evaluated in the RAINIER trial, part one of a Phase 1b/2 program initiated in August 2024 for the treatment of acute myelogenous leukemia (AML). Clinical candidate ALG.APV-527 targets 4-1BB (co-stimulatory receptor) and 5T4 (tumor antigen). The compound is designed to reactivate antigen-primed T-cells to specifically kill tumor cells and is currently being evaluated for the treatment of multiple solid tumor types.

Preclinical candidates, APVO603 and APVO711, were also developed using our ADAPTIR™ modular protein technology platform. Our preclinical candidate APVO442 was developed using our ADAPTIR-FLEX™ modular protein technology platform.

Our ADAPTIR and ADAPTIR-FLEX platforms are designed to generate monospecific, bispecific, and multi-specific antibody candidates capable of enhancing the human immune system against cancer cells. ADAPTIR and ADAPTIR-FLEX are both modular platforms, which gives us the flexibility to potentially generate immunotherapeutic candidates with a variety of mechanisms of action. This flexibility in design allows us to generate novel therapeutic candidates that may provide effective strategies against difficult to treat, as well as advanced forms of cancer. We have successfully designed and constructed numerous investigational-stage product candidates based on our ADAPTIR platform. The ADAPTIR platform technology is designed to generate monospecific and bispecific immunotherapeutic proteins that specifically bind to one or more targets, for example, bispecific therapeutic molecules, which may have structural and functional advantages over monoclonal antibodies. The structural differences of ADAPTIR and ADAPTIR FLEX molecules over monoclonal antibodies allow for the development of immunotherapies that are designed to engage immune effector cells and disease targets to produce signaling responses that modulate the immune system to kill tumor cells.

We believe we are skilled at candidate generation, validation, and subsequent preclinical and clinical development using the ADAPTIR platform and the ADAPTIR-FLEX platform to generate bispecific and multi-specific candidates or other candidates to our platform capabilities. We have developed a preclinical candidate based on the ADAPTIR-FLEX platform which is advancing in our pipeline. We are developing our ADAPTIR and ADAPTIR-FLEX molecules using our protein engineering, preclinical development, process development, and clinical development capabilities.

Recent Developments

- APVO436 received its generic name, mipletamig (mih-ple'-tah-mig), and the lead candidate will be referred to by this name moving forward.
- The Company initiated mipletamig Phase 1b/2 dose optimization trial, "RAINIER," as part of its ongoing program to evaluate the compound in combination with standard of care for frontline patients with acute myeloid leukemia (AML).
- On September 16, 2024, the Company announced data from the Phase 1 ALG.APV-527 monotherapy trial showing 60% of evaluable patients achieved stable disease in solid tumor study.

Comparison of the three and nine months ended September 30, 2024 and 2023

Research and Development Expenses

We expense research and development costs as incurred. These expenses relate primarily to conducting non-clinical studies and clinical trials, fees to professional service providers for analytical testing, consulting costs, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies, as well as costs of contract manufacturing services for clinical trial material, and costs of materials used in clinical trials and research and development. Our research and development expenses include:

- employee salaries and related expenses, including stock-based compensation and benefits for our employees involved in our drug discovery and development activities;
- consulting costs related to our clinical and pre-clinical programs;
- external research and development expense incurred under agreements with third-party contract research organizations (CRO's) and investigative sites;
- manufacturing material expense for third-party manufacturing; and
- overhead costs such as rent, utilities and depreciation.

We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, and the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials. We may experience interruption of key clinical trial activities, such as site initiation, patient enrollment and clinical trial site monitoring, and key non-clinical activities. While a number of our programs are still in the preclinical trial phase, we do not provide a breakdown of the initial associated expenses as we are often evaluating multiple product candidates simultaneously. Costs are reported in preclinical research and discovery until the program enters the clinic.

Our research and development expenses by program for the three and nine months ended September 30, 2024 and 2023 are shown in the following table:

(in thousands)	For the Three Months Ended September 30,	
	2024	2023
Clinical programs:		
Mipletamig	\$ 725	\$ 779
ALG.APV-527	556	797
Preclinical program, general research and discovery	1,822	2,311
Total	\$ 3,103	\$ 3,887
(in thousands)	For the Nine Months Ended September 30,	
	2024	2023
Clinical programs:		
Mipletamig	\$ 2,544	\$ 4,300
ALG.APV-527	2,004	2,264
Preclinical program, general research and discovery	5,950	6,952
Total	\$ 10,498	\$ 13,516

Research and development expenses decreased by \$0.8 million, from \$3.9 million for the three months ended September 30, 2023 to \$3.1 million for the three months ended September 30, 2024. Research and development expenses decreased by \$3.0 million, from \$13.5 million for the nine months ended September 30, 2023 to \$10.5 million for the nine months ended September 30, 2024. The decrease was primarily due to lower spending on mipletamig clinical trial as we concluded the Phase 1b dose expansion study while preparing to initiate a Phase 1b/2 dose optimization study and lower spending on preclinical projects and employee costs.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executive, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in research and development expenses.

General and administrative expenses decreased by \$0.6 million, from \$2.7 million for the three months ended September 30, 2023 to \$2.1 million for the three months ended September 30, 2024. General and administrative expenses decreased by \$1.3 million, from \$9.0 million for the nine months ended September 30, 2023 to \$7.7 million for the nine months ended September 30, 2024. The decrease is primarily due to lower employee and consulting costs.

Other Income (Expense), Net

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income from our cash equivalents and interest expense related to debt financing, which was paid off in Q1 2023.

Other income, net was \$0.1 million and \$0.4 million for the three and nine months ended September 30, 2024, respectively. Other income, net was \$0.2 million and \$0.4 million for the three and nine months ended September 30, 2023, respectively. The change in other income, net is primarily due to the decrease in interest income from our money market accounts.

Gain Related to Sale of Nonfinancial Asset

We recorded \$9.7 million in other income for the nine months ended September 30, 2023, due to the sale of the deferred payments and milestones to XOMA during the quarter (see Note 3).

Discontinued Operations

We did not record income from discontinued operations for the nine months ended September 30, 2024. For the nine months ended September 30, 2023, we recorded \$0.9 million of contingent gain consideration from previous discontinued operations.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our unaudited condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other factors. Although we believe that our judgments and estimates are appropriate, actual results may differ materially from our estimates and changes in these estimates are recorded when known. An accounting policy is considered critical if it is important to a company's financial condition and results of operations and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application.

Refer to Note 1 for discussion of our accounting policies, significant judgments, and estimates.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2024 and 2023:

(in thousands)	For the Nine Months Ended September 30,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ (18,026)	\$ (6,477)
Investing activities	—	—
Financing activities	8,875	2,952
Change in cash and cash equivalents	\$ (9,151)	\$ (3,525)

Net cash used in operating activities of \$18.0 million for the nine months ended September 30, 2024 was primarily due to our net loss of \$17.8 million for the period and changes in working capital accounts. Net cash used in operating activities of \$6.5 million for the nine months ended September 30, 2023 was primarily due to our net loss of \$11.5 million for the period and changes in working capital accounts.

Net cash provided by financing activities for the nine months ended September 30, 2024 of \$8.9 million was primarily due to the issuance of common stock. Net cash provided by financing activities of \$3.0 million for the nine months ended September 30, 2023 was

primarily due to \$6.4 million proceeds received from issuance of common stock and pre-funded warrants. This was offset by \$3.5 million of repayments of the MidCap term loan, which included the remaining outstanding principal balance and loan prepayment fees.

Sources of Liquidity

IXINITY Milestone Payments

On February 28, 2020, Apteko entered into an LLC Purchase Agreement with Medexus, pursuant to which we sold all of the issued and outstanding limited liability company interests of Apteko BioTherapeutics LLC, a wholly owned subsidiary of Apteko. On March 29, 2023, we entered into and closed a Purchase Agreement with XOMA pursuant to which we sold to XOMA our right, title, and interest to all future deferred payments from Medexus and a portion of potential milestones. As consideration, we received \$9.6 million at closing from XOMA and an additional \$0.05 million post-closing payment. Apteko continues to be eligible to receive up to \$5.8 million in milestone payments from Medexus upon achievement of certain regulatory and IXINITY net sales threshold. For the nine months ended September 30, 2023, Apteko received \$0.5 million in deferred payments from Medexus related to IXINITY sales for the fourth quarter of 2022.

Series A and Series B Common Warrants - August 2023

On August 4, 2023, in connection with the completion of a public offering, we issued Series A common warrants to purchase up to an aggregate of 183,281 shares of common stock and Series B common warrants to purchase up to an aggregate of 183,281 shares of common stock. The Series A and Series B common warrants are exercisable immediately following the date of issuance and will expire on August 4, 2028 and February 4, 2025, respectively. As of September 30, 2024, we have 1,316 Series A and 1,316 Series B common warrants outstanding from our August 2023 public offering with an exercise price of \$27.28 per share and 41,239 Series A common warrants outstanding with an amended exercise price of \$0.515 per share as part of the July Registered Direct Offering. If the remaining August 2023 warrants are exercised at their current exercise price, we will receive up to an additional \$0.1 million in gross proceeds.

Series A and Series B Common Warrants – November 2023

On November 9, 2023, we entered into an Inducement Agreement with certain holders of our Series A and Series B common warrants issued in connection with our August 2023 public offering to exercise for cash 140,726 Series A and 181,965 Series B common warrants at a reduced exercise price of \$10.25. We received \$3.3 million in gross proceeds from the exercise of these warrants and issued an aggregate of 645,382 new Series A and new Series B warrants. As of September 30, 2024, we have 17,524 Series A and 17,524 Series B common warrants outstanding from our November 2023 warrant inducement with an exercise price of \$10.25 per share, 82,478 Series A and 164,956 Series B common warrants with an amended exercise price of \$0.515 per share as part of the July Registered Direct Offering and 181,450 Series A and 181,450 Series B common warrants with an amended exercise price of \$0.33 per share as part of the September Registered Direct Offering. If the warrants are exercised at their current exercise price, we will receive up to an additional \$0.6 million in gross proceeds.

Common Warrants - April 2024

On April 10, 2024, we completed a public offering related to the issuance and sale of 3,400,000 shares of our common stock (or pre-funded warrants in lieu thereof) at a purchase price of \$1.35 per share. We received \$4.6 million in gross proceeds from the issuance of these shares. Our net proceeds from the offering amounted to \$4.0 million after placement agent and other fees. Additionally, we issued common warrants to purchase up to an aggregate of 6,800,000 shares of common stock. The common warrants are exercisable immediately following the date of issuance and will expire in April 2029. As of September 30, 2024, we have 133,332 common warrants outstanding from our April public offering with an exercise price of \$1.35 per share, 2,222,222 common warrants outstanding with an amended exercise price of \$0.515 per share as part of the July Registered Direct Offering and 4,444,446 common warrants outstanding with an amended exercise price of \$0.33 per share as part of the September Registered Direct Offering. If the warrants are exercised at their current exercise price, we will receive up to an additional \$2.8 million in proceeds.

Common Warrants - July 2024

On July 1, 2024, we completed the July Registered Direct Offering related to the issuance and sale of 5,339,806 shares of our common stock (or pre-funded warrants in lieu thereof) at a purchase price of \$0.515 per share. We received \$2.7 million in gross proceeds from the issuance of these shares. Our net proceeds from the offering amounted to \$2.3 million after placement agent and other fees. Additionally, we issued common warrants to purchase up to an aggregate of 10,679,612 shares of common stock. The common warrants have an exercise price of \$0.515 per share, are exercisable immediately following stockholder approval on August 6, 2024, and will expire in August 2029. The July Registered Direct Offering also amended 7,318,241 existing common warrants to lower the exercise price to \$0.515 per share. The amended warrants became exercisable immediately following stockholder approval on August 6, 2024. As of September 30, 2024, we have 3,664,184 common warrants outstanding from the July Registered Direct Offering with an exercise price of \$0.515 per share and 7,015,428 common warrants outstanding with an amended exercise price of \$0.33 per share as

part of the September Registered Direct Offering. If the warrants are exercised at their current exercise price, we will receive up to an additional \$4.2 million in proceeds.

Common Warrants - September 2024

On September 16, 2024, we completed a public offering related to the issuance and sale of 9,090,910 shares of our common stock (or pre-funded warrants in lieu thereof) at a purchase price of \$0.33 per share. We received \$3.0 million in gross proceeds from the issuance of these shares. Our net proceeds from the offering amounted to \$2.5 million after placement agent and other fees. Additionally, we issued common warrants to purchase up to an aggregate of 18,181,820 shares of common stock. The common warrants have an exercise price of \$0.33 per share, are exercisable immediately following stockholder approval on October 25, 2024, and will expire in October 2029. The September Registered Direct Offering also amended 11,822,774 existing common warrants to lower the exercise price to \$0.33 per share. The amended warrants became exercisable immediately following stockholder approval on October 25, 2024. As of September 30, 2024, we have 18,181,820 common warrants as part of the September Registered Direct Offering. If the warrants are exercised at their current exercise price, we will receive up to an additional \$6.0 million in proceeds.

Liquidity

We have financed our operations to date primarily through royalty and purchase agreements with various partners, sale of business products and segments, public offerings of our common stock, loan proceeds, milestone payments, research and development funding from strategic partners, revenue generated from our previously owned commercial products, and funds received at the date of our spin-off from Emergent. We had cash and cash equivalents of \$7.8 million and an accumulated deficit of \$241.3 million as of September 30, 2024.

For the nine months ended September 30, 2024, net cash used in our operating activities was \$18.0 million.

Our future success is dependent on our ability to develop our product candidates. We anticipate that we will continue to incur significant operating losses for the next several years as we incur expenses to continue to execute on our development strategy to advance our preclinical and clinical stage assets. We will not generate revenues from our development stage product candidates unless and/or until we or our collaborators successfully complete development and obtain regulatory approval for such product candidates, which we expect will take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for one of our development stage product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution, to the extent that such costs are not paid by collaborators. We do not have sufficient cash to complete the clinical development of any of our development stage product candidates and will require additional funding in order to complete the development activities required for regulatory approval of such product candidates. We will require substantial additional funds to continue our development programs and to fulfill our planned operating goals.

We may experience delays in opportunities to partner our product candidates, due to financial and other impacts on potential partners. Additionally, we may experience potential impacts on our future milestones from Medexus due to effects of macroeconomic impacts, including, but not limited to, bank failure, and the rising and fluctuating inflation, which may impact Medexus' ability to continue to successfully commercialize the IXINITY businesses.

There are numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical products. Accordingly, our future funding requirements may vary from our current expectations and will depend on many factors, including, but not limited to:

- Our common stock may be at risk for delisting from the Nasdaq Capital Market in the future if we do not maintain compliance with Nasdaq's continued listing requirements. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease;
- our ability to raise additional capital when needed or on acceptable terms;
- future profitability given our historical losses;
- our ability to attract, motivate and retain key personnel;
- the timing of, and the costs involved in, completing our clinical trials, and obtaining regulatory approvals for our product candidates;
- our ability to obtain regulatory clearance to commence clinical trials for product candidates;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the effects of macroeconomic conditions, including rising and fluctuating inflation, interest rates and supply chain constraints;
- our ability to successfully develop our ADAPTIR or ADAPTIR-FLEX platforms;

- the results of our current and planned preclinical studies and clinical trials;
- the scope, progress, results, and costs of researching and developing our product candidates, and of conducting preclinical and clinical trials, including whether clinical trial results will be consistent with the past data;
- our reliance on third parties to effectively conduct our clinical and non-clinical trials, and to effectively carry out their contractual duties, comply with regulatory requirements or meet expected deadlines;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, and distribution costs;
- the timing, receipt and amount of any milestone payments from Medexus with respect to IXINITY; and
- our ability to continue as a going concern.

If we are unable to raise substantial additional capital in the next year, whether on terms that are acceptable to us or at all, then we may be required to:

- delay, limit, reduce or terminate our clinical trials or other development activities for one or more of our product candidates; and/or,
- delay, limit, reduce or terminate our establishment of other activities that may be necessary to commercialize our product candidates, if approved.

The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. Due to the macroeconomic factors, we may experience delays in clinical trials and non-clinical work, and opportunities to partner our product candidates, due to financial and other impacts on potential partners.

Contractual Obligations

We have an operating lease related to our office and laboratory space in Seattle, Washington. This lease was amended in March 2019 to extend the term of the amended lease through April 2030 and provided two options to extend the lease term, each by five years, as well as a one-time option to terminate the lease in April 2023, with nine months' notice, or by July 2022. On May 26, 2022, we further amended our office and laboratory lease to remove the one-time termination option in April 2023. In exchange for removing the termination option, we received six months of free rent. As a result, we recorded an additional \$4.4 million of lease liability and right-of-use asset on the consolidated balance sheet in May 2022.

We have a non-exclusive Commercial Platform License Agreement with OMT ("OMT License Agreement") for certain transgenic rodents of OMT's OmniAb platform. Our OMT License Agreement obligates us to make milestone and royalty payments upon achievement of certain regulatory approvals and commercialization of our product candidates. Mipletamig and APVO603 are the product candidates currently subject to this agreement. Pursuant to our agreement, we are required to make a \$2.0 million milestone payment upon dosing the first patient in a Phase 2 clinical trial of mipletamig.

Our principal commitments include obligations under vendor contracts to purchase research services and other purchase commitments with our vendors. In the normal course of business, we enter into services agreements with contract research organizations, contract manufacturing organizations and other third parties. Generally, these agreements provide for termination upon notice, with specified amounts due upon termination based on the timing of termination and the terms of the agreement. The actual amounts and timing of payments under these agreements are uncertain and contingent upon the initiation and completion of the services to be provided.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of September 30, 2024, there were no material changes to the information provided under Item 7A, Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2023 filed on March 5, 2024.

Item 4. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

As of September 30, 2024, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2024, the design and operation of our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We may from time to time be named as a party to legal claims, actions and complaints, including matters involving employment claims, our intellectual property or other third-party claims. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors.

We are subject to significant risks and uncertainties that could impact the Company's businesses, results of operations and financial condition, including by causing our actual results to differ materially from those projected in any forward-looking statements. Additional risks and uncertainties that are not currently known to the Company or management or that are not currently believed by the Company or management to be material may also harm the Company's business, financial condition and results of operation. You should carefully consider the following risks and other information in this Quarterly Report on Form 10-Q in evaluating us and our common stock.

RISK FACTOR SUMMARY

The following is a summary of the material risks to our business, operations, and ownership of our common stock:

- Our common stock may be at risk for delisting from the Nasdaq Capital Market in the future if we do not maintain compliance with Nasdaq's continued listing requirements. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease.
- We have a history of losses and may not be profitable in the future.
- Our ability to continue as a going concern.
- We will require additional capital and may be unable to raise capital when needed or on acceptable terms.
- Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.
- If we experience delays or difficulties in the commencement, site initiation, enrollment of patients or completion of our clinical trials, the time to reach critical trial data and receipt of any necessary regulatory approvals could be delayed.
- Our long-term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize our product candidates.
- We may not be successful in establishing and maintaining collaborations that leverage our capabilities in pursuit of developing and commercializing our product candidates.
- We face and will continue to face substantial competition and our failure to effectively compete may prevent us from achieving significant market penetration for our product candidates, if approved.
- Our business is affected by macroeconomic conditions, including rising and fluctuating inflation, interest rates, market volatility, economic uncertainty, impact from the results of the United States presidential election and congressional elections, bank failure, and supply chain constraints.
- We may not be successful in our efforts to use and further develop our ADAPTIR or ADAPTIR-FLEX platforms.
- If we are unable to protect our intellectual proprietary rights, our business could be harmed.
- Actions of activist stockholders against us have been and could be disruptive and costly and may cause uncertainty about the strategic direction of our business.
- The results of our current and planned preclinical studies and clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities. Results from early-preclinical studies and clinical trials may not be predictive of results from later-stage or other trials and interim or top line data may be subject to change or qualification based on the complete analysis of data.
- Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified that could delay, prevent, or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

- We depend on third parties to conduct our clinical and non-clinical trials. If these third parties do not effectively carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- Our stock price is and may continue to be volatile.

- We may be subject to periodic litigation, which could result in losses or unexpected expenditure of time and resources.

- Our future income will depend, in part, on the ability of Medexus to successfully further develop, market and commercialize IXINITY, resulting in milestone payments to the Company by Medexus.

RISKS RELATED TO OUR BUSINESS

Financial Risks

We have a history of losses and may not be profitable in the future.

We have experienced significant operating losses in the past and may not be profitable in the future. For the nine months ended September 30, 2024, we had net loss of \$17.8 million compared to \$11.5 million net loss for the same period in 2023. As of September 30, 2024, we had an accumulated deficit of \$241.3 million. We expect to continue to incur annual net operating losses for the foreseeable future, and will require substantial resources over the next several years as we expand our efforts to discover, develop and commercialize immunotherapeutic candidates. Our future success and ability to attain profitability will depend upon our ability to develop and commercialize our product candidates.

Our management and board of directors have concluded that a substantial doubt is deemed to exist concerning our ability to continue as a going concern.

Accounting Standards Update, or ASU 2014-15, requires management to assess our ability to continue as a going concern for one year after the date the financial statements are issued. As further discussed in Note 1, Nature of Business and Significant Accounting Policies to our condensed consolidated financial statements in this Form 10-Q, substantial doubt is deemed to exist about the company's ability to continue as a going concern through August 2025. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern will require us to generate positive cash flow from operations, obtain additional financing, enter into strategic alliances and/or sell assets in addition to our existing cash and cash equivalents and the funding provided by our Purchase Agreement with XOMA, potential future milestone payments from Medexus under our LLC Purchase Agreement and exercise of warrants. The reaction of investors to the inclusion of a going concern statement in this report on Form 10-Q, our current lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital and enter into strategic alliances. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

We will require additional capital and may be unable to raise capital when needed or on acceptable terms.

As of September 30, 2024, we had cash and cash equivalents in the amount of \$7.8 million. We will require additional funding to continue our business including to support the ongoing clinical development of mipletamig (formerly APVO436) and ALG.APV-527, develop additional products, support commercial marketing activities or otherwise provide additional financial flexibility. If we are not able to secure adequate additional funding, we may need to make reductions in spending. This may include extending payment terms with suppliers, liquidating assets, and suspending or curtailing planned programs. We may also have to delay, reduce the scope of, suspend or eliminate one or more research and development programs. We may also be forced to grant rights to develop and market our product candidates that we would otherwise prefer to develop or market ourselves or we may be unable to take advantage of future business opportunities. A failure to raise the additional funding or to effectively implement cost reductions would harm our business, results of operations and future prospects. Our future capital requirements will depend on many factors, including:

- the cost to attract, motivate and retain key personnel;
- the level, timing and receipt of any milestone payments under our agreements with Medexus with respect to the sales of IXINITY;
- the extent to which we invest in products or technologies;
- the ability to satisfy the payment obligations and covenants under any future indebtedness;
- the ability to secure partnerships and/or collaborations that generate additional cash;
- capital improvements to our facilities;

- the scope, progress, results, and costs of our development activities;
- clinical development costs, timing, and other requirements to initiate and complete our Phase 1b/2 clinical trial for mipletamig and Phase 1 clinical trial of ALG.APV-527, as well as future clinical trials;
- the cost of preparing, filing and prosecuting patent applications, obtaining, maintaining, enforcing and protecting our intellectual property rights and defending intellectual property-related claims; and
- macroeconomic conditions, including the impact of inflation, cost of capital and the impact from the results of the United States presidential election and congressional elections.

Further, changing circumstances, some of which may be beyond our control, such as macroeconomic conditions, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We cannot guarantee that future financing will be available in sufficient amounts, or on commercially reasonable terms, or at all. If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through bank loans, public or private equity or debt offerings, collaboration and licensing arrangements, or other strategic transactions. Our ability to raise future capital on acceptable terms or at all will be impacted by the macroeconomic environment, including rising and fluctuating interest rates, economic uncertainty and volatility in the capital market, geopolitical tensions and political events, including the impact from the results of the United States presidential election and congressional elections, the ongoing war between Ukraine and Russia and the rising conflict in the Middle East, reoccurrences of COVID-19 or other pandemics, or other future widespread public health epidemics, or other factors that could also adversely impact our ability to access capital as and when needed or increase our costs in order to raise capital. Current capital market conditions, including the impact of inflation, have increased borrowing rates and can be expected to significantly increase our cost of capital as compared to prior periods. On August 4, 2023, we completed a public offering related to the issuance and sale of 183,281 shares of common stock (or pre-funded warrant in lieu thereof, all of which have since been exercised) and received net proceeds of \$4.3 million. On November 9, 2023, we entered into the Inducement Agreement to exercise for cash 322,691 existing common warrants issued on August 4, 2023, and issue 645,382 new warrants, for which we received net proceeds of \$3.0 million. On April 10, 2024, we completed a public offering related to the issuance and sale of 3,400,000 shares of our common stock (or pre-funded warrant in lieu thereof, all of which have since been exercised) and received \$4.0 million in net proceeds. On July 1, 2024, we completed the July Registered Direct Offering related to the issuance and sale of 5,339,806 shares of our common stock (or pre-funded warrant in lieu thereof, all of which have since been exercised) and received \$2.3 million in net proceeds. On September 18, 2024, we completed the September Registered Direct Offering related to the issuance and sale of 9,090,910 shares of our common stock (or pre-funded warrant in lieu thereof, of which 1,461,548 remain outstanding) and received \$2.5 million in net proceeds. Future issuances of common stock may include, but not be limited to, (i) the issuance of the remaining outstanding shares of common stock upon the exercise of warrants issued in connection with our August and November 2023 and April, July and September 2024 offerings of common stock and warrants that would result in gross proceeds of \$13.7 million, and (ii) the issuance of common stock in a firm commitment offering or private placement. Public or bank debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities, declaring dividends and limiting or restricting our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise funds by issuing equity securities, our stockholders will experience dilution. If we raise funds through collaboration and licensing arrangements with third parties or enter into other strategic transactions, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us. If financing is unavailable or lost, our business, results of operations, financial condition and financial prospects would be adversely affected and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Our Shelf Registration Statement on Form S-3 expired on December 18, 2023. SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to a shelf registration statement on Form S-3. Prior to expiration of our Shelf Registration Statement, on March 29, 2022, we filed an amendment to the prospectus related to the Shelf Registration Statement on Form S-3 filed on December 14, 2020 pursuant to General Instruction I.B.6 of Form S-3 (General Instruction I.B.6), which updated the amount of registered shares that we were eligible to sell. So long as the aggregate market value of our common stock held by non-affiliates was less than \$75 million, we would not be permitted to sell any registered shares under such Shelf Registration Statement on Form S-3 with a value of more than one-third of the aggregate market value of our common stock held by non-affiliates in any 12-month period due to the limitations of General Instruction I.B.6 of Form S-3 and the then-current public float of our common stock. If we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays in raising capital due to review by SEC staff.

Our business is affected by macroeconomic conditions, including rising and fluctuating inflation, interest rates, market volatility, economic uncertainty, and supply chain constraints.

Various macroeconomic factors have in the past and could adversely affect in the future our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such

as those resulting from the current and future conditions in the global financial markets. For instance, inflation has negatively impacted the Company by increasing our labor costs, through higher wages and higher interest rates, and operating costs. Supply chain constraints have led to higher inflation, which if sustained could have a negative impact on the Company's product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations.

We are susceptible to changes in the U.S. economy. The U.S. economy has been affected from time to time by economic downturns or recessions, supply chain constraints, rising and fluctuating inflation and interest rates, restricted credit, poor liquidity, reduced corporate profitability, volatility in credit, equity and foreign exchange markets, bankruptcies and overall uncertainty with respect to the economy.

In addition, any further deterioration in the U.S. economy would likely affect the operation of our business and ability to raise capital. In addition, U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

Actions of activist stockholders against us have been and could be disruptive and costly and may cause uncertainty about the strategic direction of our business.

Stockholders have in the past and may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our Board and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our Board or management could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our Board and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our Board or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our Board with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of a proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our Board and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Our future income will depend, in part, on the ability of Medexus to successfully further develop, market and commercialize IXINITY, resulting in milestone payments to the Company by Medexus.

On February 28, 2020, we entered into a Purchase Agreement with Medexus, pursuant to which we sold all of the issued and outstanding limited liability company interests of Aptev BioTherapeutics, a subsidiary of Aptev that wholly owns the IXINITY and related Hemophilia B business. We are entitled to receive future potential payments to the extent of the achievement of certain regulatory and commercial milestones and through deferred payments based on net sales of IXINITY. Royalties were earned at the rate of 2% of net revenue through June 2022. As of June 30, 2022, the royalty rate on net revenue of IXINITY increased to 5%. On March 29, 2023, we entered into and closed a Purchase Agreement with XOMA pursuant to which we sold to XOMA our right, title, and interest to all future deferred payments from Medexus and a portion of potential milestones. As consideration, we received \$9.6 million at closing from XOMA and an additional \$0.05 million post-closing payment. We accounted for the \$9.6 million Closing Payment and the \$0.05 million post-closing payment from XOMA as other income in accordance with ASC 610-20 Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets in the first quarter of 2023.

We no longer control the development, marketing, and commercialization of IXINITY and are dependent on Medexus to successfully do so. Although Medexus has agreed to use commercially reasonable efforts to commercialize IXINITY in the ordinary course of business in good faith, Medexus may not commit adequate resources to the further development, marketing, and commercialization of IXINITY, may experience financial difficulties, may face competition, or may prioritize other products or initiatives. Medexus' ability to continue to successfully commercialize the IXINITY business may be affected, and we may experience potential impacts on our future milestone payments from Medexus due to the macroeconomic and geopolitical environment. The failure

of Medexus to successfully market and commercialize IXINITY, including because of factors outside of Medexus' control, could result in lower than expected milestone payments to us and negatively impact our future financial and operating results.

Our operating results are unpredictable and may fluctuate.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year, as a result of a variety of factors, including:

- the level and timing of any milestone payments with respect to sales of IXINITY by Medexus;
- the extent of any payments received from collaboration arrangements and development funding as well as the achievement of development and clinical milestones under collaboration and license agreements that we may enter into from time to time and that may vary significantly from quarter to quarter; and,
- the timing, cost, and level of investment in our research and development and clinical activities as well as expenditures we may incur to acquire or develop additional technologies, products and product candidates.

Due to the macroeconomic and geopolitical environment, we may experience delays in opportunities to partner our product candidates, due to financial and other impacts on potential partners. Additionally, we may experience potential impacts on our future milestone payments from Medexus, which may impact Medexus' ability to continue to successfully commercialize the IXINITY businesses. These and other factors may have a material adverse effect on our business, results of operations and financial condition.

We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition, and results of operations.

The nature of our business exposes us to potential liability inherent in pharmaceutical products, including with respect to the testing of our product candidates in clinical trials and any product candidates that we successfully develop. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that sell any products that we successfully develop. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise receive regulatory approval for study or commercial sale. We cannot predict the frequency, outcome or cost to defend any such claims.

If we cannot successfully defend ourselves against future claims that our product candidates caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- adverse publicity and/or injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- decreased demand or withdrawal of an approved product;
- loss of revenue; and
- the inability to commercialize products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, and results of operations. The cost of defending any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability claims, regardless of merit or eventual outcome, may absorb significant management time and result in reputational harm, potential loss of revenue from decreased demand for any product candidates we successfully develop, withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs, and could cause our stock price to fall.

Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. If we are unable to retain the services of one or more of the principal members of senior management, including our Chief Executive Officer, Marvin L. White, our Chief Operating Officer, Jeffrey G. Lamothe, our Chief Financial Officer, Daphne Taylor, our General Counsel, SoYoung Kwon, or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biotechnology and pharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package or otherwise attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

We completed a Section 382 study and have concluded that we experienced an "ownership change" as defined in Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), and thus the tax benefits of our pre-"ownership change" net operating loss carryforwards and certain other tax attributes will be subject to an annual limitation under Sections 382 and 383 of the Code.

In general, a corporation undergoes an "ownership change" under Section 382 of the Code if, among other things, the stockholders who own, directly or indirectly, 5% or more of the corporation's stock (by value), or are otherwise treated as "5% stockholders" under Section 382 of the Code and the Treasury regulations promulgated thereunder, increase their aggregate percentage ownership (by value) of the corporation's stock by more than 50 percentage points over the lowest percentage of stock owned by the 5% stockholders at any time during the applicable testing period, which is generally the rolling three-year period preceding the date of the potential ownership change testing event. Such potential ownership change testing events include changes involving a stockholder becoming a 5% stockholder or arising from a new issuance of capital stock or share repurchases by the corporation, subject to certain exceptions.

In the event of an "ownership change," Sections 382 and 383 of the Code impose an annual limitation on the amount of taxable income a corporation may offset with pre-change net operating loss carryforwards and certain other tax attributes. The annual limitation is generally equal to the value of the outstanding stock of the corporation immediately before the ownership change (excluding certain capital contributions), multiplied by the long-term tax-exempt rate as published by the IRS for the month in which the ownership change occurs (the long-term tax-exempt rate for June 2024 is 3.44%). Any unused annual limitation may generally be carried over to subsequent years until the pre-ownership change net operating loss carryforwards and certain other tax attributes expire or are fully utilized by the corporation. Similar provisions of state tax law may also apply to limit the use of state net operating loss carryforwards and certain other tax attributes.

Additionally, Section 382 of the Code includes special rules that apply to a corporation with a significant amount of net unrealized built-in gains or net unrealized built-in losses in its assets immediately prior to ownership change under Section 382 of the Code. In general, certain built-in gains recognized during the five-year period beginning on the date of the ownership change increases the corporation's annual limitation under Sections 382 and 383 of the Code in the taxable year that such built-in gains are recognized or deemed recognized (but only up to the amount of the net unrealized built-in gain), while certain built-in losses recognized during such five-year period are subject to the annual limitation under Section 382 of the Code (but only up to the amount of the net unrealized built-in loss).

As of December 31, 2023, we had approximately \$168.2 million and \$70.5 million of federal and state net operating loss carryforwards, respectively, available to reduce future taxable income that will begin to expire in 2037 for federal income tax purposes. We completed an IRC Section 382 study through December 31, 2023. The study concluded that we have experienced an ownership change in November of 2020 and December of 2020 and \$162.6 million of our net operating loss ("NOL") carryforwards are subject to an annual limitation. It is not expected that the annual limitations will result in the expiration of NOL carryforwards prior to utilization assuming sufficient income.

We cannot predict or control the occurrence or timing of another ownership change under Section 382 of the Code in the future. In addition, it is possible that any offering of securities by us could result in an ownership change. If another ownership change were to occur, future limitations could apply to our net operating losses and certain other tax attributes, which could result in a material amount of our net operating loss carryforwards and certain other tax attributes becoming unavailable to offset future income tax liabilities.

The realization of all or a portion of our deferred income tax assets (including net operating loss carryforwards) is dependent upon the generation of future income during the statutory carryforward periods. Our inability to utilize our limited pre-ownership change net operating loss carryforwards and certain other tax attributes, or the occurrence of a future ownership change and resulting additional limitations to these tax attributes, could have a material adverse effect on our financial condition, results of operations and cash flows.

The change to the deductibility of our research and development expenditures enacted under the Tax Cuts and Jobs Act ("TCJA") could increase the amount of taxes to which we are subject and our effective tax rate.

Beginning in 2022, the TCJA eliminates the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize these expenditures over five or fifteen years depending on the type of research and development expenditure pursuant to Section 174 of the Code. Such change to the deductibility of our research and development expenditures could increase the amount of taxes to which we are subject and our effective tax rate.

Our investments are subject to market and credit risks that could diminish their value and these risks could be greater during periods of extreme volatility or disruption in the financial and credit markets, which could adversely impact our business, financial condition, results of operations, liquidity and cash flows.

Our investments are subject to risks of credit defaults and changes in market values. Periods of macroeconomic weakness or recession, heightened volatility or disruption in the financial and credit markets, such as the current macroeconomic environment, increase these risks, potentially resulting in other-than-temporary impairment of assets in our investment portfolio. The impact of geopolitical tension or political events, such as the impact from the United States presidential election and congressional elections, a deterioration in the bilateral relationship between the US and China, the rising conflict in the Middle East, or Russia's invasion of Ukraine, including any additional sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries against governmental or other entities in, for example, Russia, also could lead to disruption, instability and volatility in the global markets, which may have an impact on our investments across negatively impacted sectors or geographies. Severe global economic and societal disruptions and uncertainties, such as reoccurrences of COVID-19 or other pandemics, or other future widespread public health epidemics may cause disruptions that could severely impact our business, such as delays or difficulties to the financing environment and raising capital due to economic uncertainty or volatility.

Product Development Risks

The results of our current and planned preclinical studies and clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities. Results from early preclinical studies and clinical trials may not be predictive of results from later-stage or other trials and interim or top line data may be subject to change or qualification based on the complete analysis of data.

We completed our Phase 1b dose expansion clinical trial with mipletamig in 2023 and initiated a dose optimization Phase 1b/2 study in August of 2024 to assess safety and efficacy of mipletamig and to determine an optimal dose in front line patients. Additionally, we initiated a first-in-human Phase 1 clinical study of ALG-APV-527 in the first quarter of 2023 and we are currently enrolling new patients. None of our other product candidates have entered clinical development. Clinical failure can occur at any stage of preclinical or clinical development. Preclinical studies and clinical trials may produce inconsistent, negative or inconclusive results. The FDA or a non-U.S. regulatory authority may require us to conduct additional clinical or preclinical testing. Success in early preliminary data, preclinical studies and clinical trials does not mean that future larger registration clinical trials will be successful and interim results of a clinical trial do not necessarily predict final results. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical trials. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies whose product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if early-stage clinical trials are promising, we may need to conduct additional clinical trials of our product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Any of these events could limit the commercial potential of our product candidates and have a material adverse effect on our business, prospects, financial condition and results of operations. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

In addition, our mipletamig clinical trial is an open-label study and is 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 an existing approved drug. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels or in combination with other drugs. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved

merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from these clinical trials may not be predictive of future clinical trial results with mipletamig or other product candidates. In addition, although the FDA issued a "may proceed" notification which allowed us and Alligator to initiate our Phase 1 clinical trial of ALG.APV-527, and the interim data from the dose escalation phase are positive, we cannot guarantee that this trial or future trials of ALG.APV-527 will show the desired safety and efficacy.

We may publicly disclose top line or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. The top line or interim 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. Even in situations where a clinical stage candidate appears to be benefiting a patient that benefit may not be of a permanent nature. Top line and interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. In addition, the achievement of one primary endpoint for a trial does not guarantee that additional co-primary endpoints or secondary endpoints will be achieved. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

Our future clinical trials may not be successful. Moreover, should there be a flaw in a clinical trial, it may not become apparent until the clinical trial is well advanced. We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or Institutional Review Boards ("IRBs") may not authorize us or our investigators to commence or continue a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators or IRBs may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our contract research organizations ("CROs");
- regulators may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing, surveillance, or Risk Evaluation and Mitigation Strategy ("REMS") requirements to maintain regulatory approval;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance;
- changes in marketing approval policies, laws, regulations, or the regulatory review process during the development period rendering our data insufficient to obtain marketing approval;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a marketing application;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from non-clinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;

- the FDA or comparable regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our contract manufacturer's manufacturing facility for clinical and future commercial supplies; and
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. Regardless of any advisory committee recommendation, the FDA may decline to approve the biologics license application ("BLA") for a number of reasons including, if the clinical benefit, safety profile or effectiveness of the drug is not deemed by the FDA to warrant approval. The FDA or other non-U.S. regulatory authorities may disagree with our trial design, and our interpretation of data from non-clinical studies and clinical trials. In particular, the FDA may not view our data as being clinically meaningful or statistically persuasive. The regulatory authorities and policies governing the development of our product candidates may also change at any time. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial. Any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

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

We have submitted INDs and received approvals to proceed into clinical trials for multiple product candidates, including ALG-APV-527 and mipletamig, however, we may not be able to file future INDs for our 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 future INDs will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

If we experience delays or difficulties in the commencement, site initiation, enrollment of patients or completion of our clinical trials, the time to reach critical trial data and receipt of any necessary regulatory approvals could be delayed.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate, enroll and maintain a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Furthermore, mipletamig has received orphan drug designation for acute myelogenous leukemia and thus has a relatively small patient population. Also, the eligibility criteria of our clinical trials may further limit the pool of available study participants as we require that patients have specific characteristics that we can measure to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the design of the clinical trial, including the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experiences;
- our ability to obtain and maintain patient consents;
- the ability to monitor patients adequately during and after treatment;
- reporting of preliminary results of any of our clinical trial sites; and

- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials could result in significant delays and could require us to abandon one or more clinical trials altogether. Site initiation and enrollment delays in our clinical trials may result in increased development costs for our product candidates, delays in the availability of preliminary or final results, and delays to commercially launching our product candidates, if approved, which may cause the value of our company to decline and limit our ability to obtain additional financing.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified that could delay, prevent, or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of any of our product candidates, either when used alone or in combination with other approved or investigational therapies, could cause us or regulatory authorities to interrupt, delay or halt our development activities and manufacturing and distribution operations and could result in a more restrictive label, the imposition of a clinical hold, suspension, distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If any of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon their development or limit development to certain 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. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

As we continue developing our product candidates and conduct clinical trials of our product candidates, serious adverse events, or SAEs, undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. Undesirable side effects, or other unexpected adverse events or properties of any of our product candidates, could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, the FDA or comparable foreign regulatory authorities could suspend or terminate a clinical trial or deny approval of our product candidates. Furthermore, we are currently and may in the future evaluate our product candidates in combination with approved and/or experimental therapies. These combinations may have additional or more severe side effects than caused by our product candidate as monotherapies. The uncertainty resulting from the use of our product candidate in combination with other therapies may make it difficult to accurately predict side effects or efficacy in potential future clinical trials. If our product candidates receive marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences may result, including:

- regulatory authorities may require us to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- regulatory authorities may require one or more post-market studies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- regulatory authorities may require implementation of a REMS, Field Safety Corrective Actions or equivalent, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market approval and acceptance of the affected product candidate, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and materially harm our business and results of operations.

We depend on third parties to conduct our clinical and non-clinical trials. If these third parties do not effectively carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct the clinical and preclinical trials required to obtain regulatory approval for our product candidates. We depend on third parties, such as independent clinical investigators, research sites, contract research

organizations, or CROs, and other third-party service providers to conduct the clinical and preclinical trials of our product candidates, and we expect to continue to do so. For example, Dr. Dirk Huebner, Chief Medical Officer, is providing clinical trial and medical affairs oversight duties as an independent consultant. We rely heavily on Dr. Huebner and these other third parties for successful execution and oversight of our clinical and non-clinical trials, but we do not exercise day to day control over their activities.

While we have agreements governing the activities of third parties, we have limited influence and control over their actual performance and activities. For instance, our third-party service providers are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, and non-clinical programs. Our third-party service providers may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our non-clinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions.

Our reliance on third-party service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with the FDA-approved good clinical practices, or GCPs, and the plans and protocols contained in the relevant regulatory application. In addition, these organizations and individuals may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult and/or costly and result in a delay of our trials. In addition, business disruptions arising from circumstances out of our control, could negatively affect the ability of some of the independent clinical investigators, contract research organizations and other third-party service providers that conduct our clinical and preclinical trials of our product candidates. Any delay in or inability to complete our trials could delay or prevent the development, approval, and commercialization of our product candidates.

If CROs or other third parties assisting us or our study sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We or they may also face regulatory enforcement action. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with GCP. In addition, our clinical trials must be conducted with product produced under GMP and similar regulations outside of the United States. Our failure, or the failure of our product candidate manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, or conduct additional trials, which would increase our development costs and delay or impact the conduct of our preclinical studies, clinical trials, and the likelihood of regulatory approval.

If third parties do not carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated.

Agreements with third parties conducting or otherwise assisting with our clinical or non-clinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third-party commences work. As a result, if we need to enter into alternative arrangements, it could delay our product development activities and adversely affect our business. Though we carefully manage our relationships with our third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

If any of these events occur, we may not be able to obtain regulatory approval of our product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products. Moreover, if we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

Manufacture of our product candidates, especially in large quantities, is complex and time consuming. The loss of any of our third-party manufacturers, or delays or problems in the manufacture of our product candidates, could result in product shortages and/or delays in clinical development.

We do not have manufacturing capabilities and do not plan to develop such capacity in the foreseeable future. We depend on a limited number of third-party suppliers for the production of our product candidates. Accordingly, our ability to develop and deliver product candidates in a timely and competitive manner and to enable us to conduct our development programs depends on our third-party manufacturers being able to continue to meet our ongoing clinical trial needs and perform their contractual obligations. In order to successfully develop and commercialize our product candidates in a timely manner, we and our third-party manufacturers must be able to develop and execute on manufacturing processes and reach agreement on contract terms.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or any product that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

If these third-party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture and/or store our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to expand capacities to support commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to produce, or may be delayed in producing sufficient product candidates to meet our supply requirements. Any delays in obtaining adequate supplies with respect to our product candidates and components may delay the development or commercialization of our product candidates.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates, components, and programs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so.

If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product or component for commercial sale or for our clinical trials should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. These third-party facilities may also be affected by natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory findings following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to an alternate supplier in a timely fashion if at all. The addition of a new or alternative manufacturer may also require FDA approvals and may have a material adverse effect on our business.

If for any reason we are unable to obtain adequate supplies of our product candidates or the components used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

We or our third-party manufacturers may also encounter shortages in the raw materials or therapeutic substances necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by our competitors or others. We may also not be able to obtain such materials on favorable terms as a result of global trade policies. Our third-party manufacturers' failure to obtain the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.

All of our current product candidates are biologics. Our product candidates must be made consistently and in compliance with a clearly defined manufacturing process. Problems may arise during manufacturing for a variety of reasons, including problems with raw materials, equipment malfunction or replacement and failure to follow specific protocols and procedures. Slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation and contamination including from, among other things, particulates, filtration, filling, labeling, packaging, storage and shipping, and quality control testing, may result in lot failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action.

Additionally, our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage or conduct our clinical trials, manufacture our product candidates and market and sell our products outside

of the United States and maintain our existing arrangements with respect to the commercialization or manufacture of our products. We may not have the expertise or the resources to conduct all of these activities for all products and product candidates on our own and, as a result, are particularly dependent on third parties in many areas. Any current or future arrangements for development and commercialization may not be successful, as the amount and timing of resources that third parties devote to developing, manufacturing, and commercializing our products candidates are not within our control. If we are not able to establish or maintain agreements relating to our product candidates in development, our results of operations and prospects would be materially and adversely affected.

Any loss of a third-party manufacturer, any delays, or problems in the manufacture of our products, or termination of any arrangements for development and commercialization of our products could have a material adverse effect on our business, operations, results of operations and financial condition. We may be required to replace our manufacturer and if this were to occur, we may incur added costs and delays in identifying and qualifying any such replacements. We may also not be able to enter into such arrangements on favorable commercial terms.

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

As product candidates are developed through preclinical studies to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, clinical trials, FDA notification, or FDA approval. Any of the foregoing could limit our future revenues and growth.

Failure of our third-party manufacturers to successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, may prevent regulatory approval of those manufacturing facilities.

We rely on third parties to manufacture all clinical trial materials for our product candidates, and we will rely on third parties to manufacture commercial supplies, if any such product candidates are ultimately approved for commercial sale. Manufacturers of our product candidates and therapeutic substances must comply with GMP requirements enforced by the FDA that are applicable to both finished products and their active components used both for clinical and commercial supply. The FDA enforces these requirements through its facilities inspection program. Our product candidates, including mipletamig and ALG.APV-527, will not be approved for marketing by the FDA or other foreign regulatory authorities unless the FDA or their foreign equivalents also approve the facilities used by our third-party manufacturers to produce them for commercialization. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's or foreign regulatory authorities' strict regulatory requirements, the FDA or their foreign counterparts will not approve their manufacturing facilities, which would result in significant delays in obtaining FDA or foreign marketing approvals for our product candidates. If this were to occur, we may also never receive marketing approval, we may need to repeat clinical trials, we may need to undertake costly corrective actions, including product recalls, we may risk harm to subjects or patients, and we may face enforcement actions.

While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain and maintain regulatory approval for or market our product candidates, if approved. Additionally, we may be unable to contract with alternative manufacturers on favorable or reasonable terms. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new 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 manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or any other regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. This would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another manufacturer produce our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. We must also receive FDA approval for the use of any new manufacturers for commercial supply.

We and our third-party manufacturers may not be able to meet these manufacturing process requirements for any of our current product candidates, all of which have complex manufacturing processes, which make meeting these requirements even more challenging. If we are unable to develop manufacturing processes for our clinical product candidates that satisfy these requirements, we will not be able to supply sufficient quantities of test material to conduct our clinical trials in a timely or cost-effective manner, and as a result, our development programs will be delayed, our financial performance will be adversely impacted and we will be unable to meet our long-term goals.

Certain of our product candidates have received orphan drug designation from the FDA. However, there is no guarantee that we will be able to maintain this designation, receive this designation for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.

Certain of our product candidates have received orphan drug designation. We may also seek orphan drug designation for our other product candidates, as appropriate. While orphan drug designation does provide us with certain advantages, it neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

Generally, if a product candidate with orphan drug designation subsequently receives marketing approval before another product considered by the FDA to be the same for the same orphan indication, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for the same indication for a period of seven years in the United States.

We may not be able to obtain any future orphan drug designations that we apply for. Orphan drug designations do not guarantee that we will be able to successfully develop our product candidates, and there is no guarantee that we will be able to maintain any orphan drug designations that we receive. For instance, orphan drug designations may be revoked if the FDA finds that the request for designation contained an untrue statement of material fact or omitted material information, or if the FDA finds that the product candidate was not eligible for designation at the time of the submission of the request.

Moreover, even if we are able to receive and maintain orphan drug designations, we may ultimately not receive any period of regulatory exclusivity if our product candidates are approved. For instance, we may not receive orphan product regulatory exclusivity if the indication for which we receive FDA approval is broader than the orphan drug designation. Orphan exclusivity may also be lost for the same reasons that orphan drug designation may be lost. Orphan exclusivity may further be lost if we are unable to assure a sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan exclusivity for any of our current or future product candidates, that exclusivity may not effectively protect the product from competition as different products can be approved for the same condition or products that are the same as ours can be approved for different conditions. Even after an orphan product is approved, the FDA can also subsequently approve a product containing the same principal molecular features for the same condition if the FDA concludes that the later product is clinically superior. The FDA may further grant orphan drug designation to multiple sponsors for the same compound or active molecule and for the same indication. If another sponsor receives FDA approval for such product before we do, we would be prevented from launching our product in the United States for the orphan indication for a period of at least seven years, unless we can demonstrate clinical superiority. Moreover, third-party payors may reimburse for products off-label even if not indicated for the orphan condition.

We may seek Breakthrough Therapy designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if the product candidates we develop qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification and rescind the designation.

We may seek designation for our ADAPTIR and ADAPTIR-FLEX platform technologies as a designated platform technology, but we might not receive such designation, and even if we do, such designation may not lead to a faster development, regulatory review or approval process.

We may seek designation for our ADAPTIR and ADAPTIR-FLEX platform technologies as a designated platform technology. Under the FDORA, a platform technology incorporated within or utilized by a biologic is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a product approved under a BLA; (2) preliminary evidence submitted by the sponsor of the approved or licensed product, or a sponsor that has been granted a right of reference to data submitted in the application for such product, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one product without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a product that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original BLA for a product that uses or incorporates the platform technology. Even if we believe our platform technology meets the criteria for such designation, the FDA may disagree and instead determine not to grant such designation. In addition, the receipt of such designation for a platform technology does not ensure that a product will be developed more quickly or receive a faster FDA review process or ultimate FDA approval. Moreover, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

We have in the past and may in the future conduct clinical trials for our product candidates outside the United States, and the FDA or non-U.S. regulatory authorities may not accept data from such trials in the development or approval of our product candidates in those jurisdictions.

We have in the past and may in the future conduct clinical trials outside the U.S. and the FDA and foreign regulatory authorities may not accept those data in support of the further development or approval of our product candidates. The acceptance of trial data from clinical trials conducted outside the United States by the FDA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements.

In addition, such foreign trials will be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need to conduct additional trials beyond those we have planned, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving marketing approval for commercialization in the applicable jurisdiction.

Commercialization Risks

Our ability to grow revenues and execute on our long-term strategy depends heavily on our ability to discover, develop, and obtain marketing approval for our product candidates.

We currently have no products approved for commercial distribution. We have invested a significant portion of our efforts and financial resources in the development of our product candidates. Our business depends on the successful development and commercialization of our product candidates, which will require additional clinical and preclinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment, which may never occur. Our ability to generate revenues is substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates. Except for the revenues from previously sold products, we currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product.

In order for us to achieve our long-term business objectives, we will need to successfully discover and/or develop and commercialize our product candidates. Although we have made, and expect to continue to make, significant investments in research and development, we have had only a limited number of our internally-discovered product candidates reach the clinical development stage. We currently have two clinical-stage candidates, mipletamig and ALG-APV-527, which were built on the ADAPTIR platform. Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of

unexpected or unacceptable adverse events or failure to demonstrate efficacy in clinical trials. Failure to successfully discover and/or develop, obtain marketing approval for and commercialize additional products and product candidates would likely have a material adverse effect on our ability to grow revenues and improve our financial condition. If we are required to conduct additional clinical trials or other testing of our product candidates that we develop beyond those that we currently expect, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may be delayed in obtaining marketing approval for our product candidates, not obtain marketing approval at all, obtain approval for limited indications or patient populations, with a label without claims necessary for us to successfully market our products, or with significant labeled warnings. We may also be subject to additional post-marketing testing requirements, surveillance requirements, or REMS. To the extent any of the foregoing should occur, our business may be materially harmed.

We may not be successful in our efforts to use and further develop our ADAPTIR or ADAPTIR-FLEX platforms.

A key element of our strategy is to expand our product pipeline of immuno-oncology candidates based on our ADAPTIR and ADAPTIR-FLEX platform technologies. We plan to select and create product candidates for early development, potentially with other collaborative partners. We expect to continue to develop the platform to address unmet medical needs through directed immune stimulatory and/or blockades in oncology and other therapeutic areas. Our goal is to leverage our technology to make targeted investment in monospecific, bispecific, and multi-specific ADAPTIR and ADAPTIR-FLEX therapeutics. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based on our ADAPTIR and ADAPTIR-FLEX platform technologies, our ability to obtain product revenues in future periods may be adversely affected, which likely would result in harm to our financial position and our financial prospects, and adversely affect our stock price.

We face and will continue to face substantial competition and our failure to effectively compete may prevent us from achieving significant market penetration for our product candidates, if approved.

The development and commercialization of new biotechnology products is highly competitive and subject to rapid technological advances. We may face future competition with respect to our current product candidates and any product candidates we may seek to develop or commercialize in the future obtained from other companies and governments, universities, and other non-profit research organizations. Our competitors may develop products that are safer, more effective, more convenient, or less costly than any products that we may develop or market, or may obtain marketing approval for their products from the FDA, or equivalent foreign regulatory bodies more rapidly than we may obtain approval for our product candidates. Our competitors may have greater resources and may devote greater resources to research and develop their products, research and development capabilities, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition or macroeconomic impacts more successfully, or more effectively negotiate third-party licensing and collaborative arrangements.

We believe that our most significant competitors in the oncology market include: AbbVie Inc., Affimed, ALX Oncology Holdings Inc., Amgen Inc., Arcellx, AstraZeneca, AvenCell Therapeutics, Inc., BioNTech, Bio-Path, Bristol Myers Squibb, Cellectis, Faron Pharma, F-star Therapeutics, Genentech Inc. (a subsidiary of F. Hoffmann-La Roche Ltd.), Genmab A/S, Gilead Sciences, Inc., GlaxoSmithKline plc, ImmunoGen, Inc., Johnson & Johnson, Macrogenics, Inc., Menarini Group, Molecular Partners, Novartis, Pfizer Inc., Pieris Pharmaceuticals, Inc., Regeneron Pharma, Sanofi-Aventis US LLC, Shattuck Labs, Syros Pharmaceuticals, Inc., Servier Laboratories, Xencor, Inc., and Zymeworks Biopharmaceuticals, Inc. We expect to compete on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed. If we are not successful in demonstrating these attributes, physicians and other key healthcare decision makers may choose other products over any products we successfully develop, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition and results of operations.

Any of our product candidates, if approved, may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The success of our product candidates, if approved, will depend upon, among other things, their acceptance by physicians, patients, third-party payors, and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If any of our product candidates do not achieve and maintain an adequate level of acceptance, we may not generate material revenues from sales of these products. The degree of market acceptance of our products will depend on a number of factors, including: our ability to provide acceptable evidence of safety and efficacy; the prevalence and severity of any side effects; availability, relative cost and relative efficacy of alternative and competing treatments; the ability to offer our products for sale at competitive prices; our ability to continuously supply the market without interruption; the relative convenience and ease of administration; the willingness of the target patient population to try new products and of physicians to prescribe these products; the strength of marketing and distribution support; publicity concerning our products or competing products and treatments; and the sufficiency of coverage or reimbursement by third parties.

Legislative or healthcare reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to legal and political challenges, as well as efforts to repeal, replace, delay, circumvent, or loosen certain aspects of the ACA or mandates required thereby. Additionally, Congress has considered legislation that would repeal or replace and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties as of January 1, 2019 for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the Budget Control Act of 2011 among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction occurred beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction resumed on July 1, 2022.
- On May 30, 2018, the 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 drug products 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 pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2 percent per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken.

Additionally, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products, including by tying reimbursement to the price of products in other developed countries. For example, proposals have been made to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical 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. Legislative and regulatory agendas, as they relate to the healthcare and pharmaceutical industries and the economy as a whole, of the Biden administration and the U.S. Congress currently remain uncertain. One example of President Biden's priorities came via an executive order that he issued on July 9, 2021 directing the FDA to, among other things, continue to clarify and improve the approval framework for biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede biosimilar competition. Any new laws and initiatives may result in additional reductions in Medicare and other healthcare funding or impose additional regulatory requirements on drug development or approval, which could have a material adverse effect on our future customers and accordingly, our financial operations.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidates we successfully develop or additional pricing pressures.

Regulatory and Compliance Risks

Our long-term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize our product candidates.

Our product candidates and the activities associated with their development, including testing, manufacture, recordkeeping, storage, and approval, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have limited resources for use in preparing, filing, and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

The FDA and other comparable regulatory agencies in foreign countries impose substantial and rigorous requirements for the development, production, marketing authorization and commercial introduction of drug products. These requirements include non-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials, and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory authorities, including the FDA evolve in their staff interpretations and practices and may impose more stringent or different requirements than currently in effect, which may adversely affect our planned and ongoing drug development and/or our sales and marketing efforts.

In the United States, to obtain approval from the FDA to market any of our future biologic products, we will be required to submit a BLA to the FDA. Ordinarily, the FDA requires a sponsor to support a BLA with substantial evidence of the product's safety, purity, and potency in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase 3 safety and efficacy trials conducted in patients with the disease or condition being targeted.

Developing and obtaining regulatory approval for product candidates is a lengthy process, often taking a number of years, is uncertain and expensive. All of the product candidates that we are developing, or may develop in the future, require research and development, non-clinical studies, non-clinical testing, and clinical trials prior to seeking regulatory approval, and commencing commercial sales. In addition, we may need to address a number of technological challenges in order to complete development of our product candidates. As a result, the development of product candidates may take longer than anticipated or not be successful at all.

Our product candidate development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any non-clinical tests or clinical trials above what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do. This may prevent us from receiving marketing approvals and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. If any of this occurs, our business, financial condition, results of operations, and prospects will be materially harmed.

Generally, no product can receive FDA approval, marketing authorization from the European Commission or the competent authorities of the EU Member States, or approval from comparable regulatory agencies in foreign countries unless data generated in human clinical trials demonstrates both safety and efficacy for each target indication in accordance with such authority's standards.

The large majority of product candidates that begin human clinical trials fail to demonstrate the required safety and efficacy characteristics necessary for marketing approval. Failure to demonstrate the safety and efficacy of any of our product candidates for each target indication in clinical trials would prevent us from obtaining required approvals from regulatory authorities, which would prevent us from commercializing those product candidates. Negative or inconclusive results from the clinical trials or adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that additional trials be conducted, any of which may not be clinically feasible or financially practicable, that the conduct of trials be suspended, or that a program be terminated.

Any regulatory approval we ultimately obtain may limit the indicated uses for the product or subject the product to restrictions or post-approval commitments that render the product commercially non-viable. Securing regulatory approval requires the submission of extensive non-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the regulatory authorities for each therapeutic indication to establish the product's safety and efficacy. If we are unable to submit the necessary data and information, for example, because the results of clinical trials are not favorable, or if the applicable regulatory authority delays reviewing or does not approve our applications, we will be unable to obtain regulatory approval.

Delays in obtaining or failure to obtain regulatory approvals may delay or prevent the successful commercialization of any of the products or product candidates in the jurisdiction for which approval is sought; diminish our competitive advantage; and defer or decrease our receipt of revenue.

Some of our product candidates previously in development experienced regulatory and/or clinical setbacks. Clinical development has been discontinued for product candidates olertuzumab, APVO414, and APVO210. Both APVO414 and APVO210 were discontinued after patients developed ADA. Most recently, in 2019, we elected to discontinue the APVO210 development program following the review of data from the Phase 1 multiple ascending dose (MAD) clinical study of APVO210 in healthy volunteers that suggests that APVO210 would not meet the desired target product profile for future commercialization. Specifically, the clinical data showed evidence of increasing titers of ADA with repeated doses of APVO210, which had varying impact on APVO210 drug levels in subjects' blood. The cause of the ADA is uncertain; however, we believe that appearance of ADA is related to the mechanism of action of APVO210, and not due to the structure, or sequences characteristic of the ADAPTIR platform. Although we have re-designed certain components of the ADAPTIR platform based on what we have learned in prior clinical trials, there is no guarantee that the occurrence of ADA or other clinical setbacks will not occur in the development of our existing and future ADAPTIR product candidates.

The procedures to obtain marketing approvals vary among countries and can involve additional clinical trials or other pre-filing requirements. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all the risks associated with obtaining FDA approval, or different or additional risks. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. Accordingly, approval by the FDA does not ensure approval by the regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by the FDA or regulatory authorities in other foreign countries. Failure to obtain regulatory approval in one jurisdiction, however, may impact the decision of other jurisdictions. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products and products in development in any market on a timely basis, if at all.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our product candidates are and will continue to be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

We and our product candidates are subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities, including requirements related to the conduct of clinical and non-clinical studies, manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such products. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with GMP-requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to GMP requirements and applicable product tracking and tracing requirements.

FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may, among other actions, withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our collaborators could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with GMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers

or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various results, including:

- restrictions on manufacturing or distribution, or marketing of such products;
- modifications to promotional pieces and product labels;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or a similar strategy;
- changes to the way the product is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining product approval and market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent us from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

The FDA's policies may change and additional government laws and regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates, that could limit the marketability of our product candidates, or that could impose additional regulatory obligations on us. For example, the current administration may implement new or revised laws, regulatory requirements, and associated compliance obligations, as well as postponed or frozen regulatory requirements. Changes in medical practice and standard of care may also impact the marketability of our product candidates. If we are slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, they could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

If we fail to comply with foreign, federal, state, and local healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a biotechnology company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid, or other third-party payors for our products, certain federal, state, local and foreign healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. We are subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, to induce, or in return for, either the referral of an individual, or the purchase, lease, prescribing or recommendation of an item, good, facility or service reimbursable by a federally funded healthcare program, such as the Medicare or Medicaid program. The term "remuneration" has been interpreted broadly and may constrain our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities, among other activities;
- federal civil and criminal false claims, including the federal False Claims Act, and false statement laws and civil monetary penalty laws, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, on individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent or knowingly making any materially false statement in connection with the delivery or payment for healthcare benefits, items or services;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of 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 statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. 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, or HITECH, and their respective implementing regulations mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy, security and transmission of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates", or independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, biologics, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the CMS, certain payments and transfers of value made to physicians and teaching hospitals, and ownership or investment interests held by physicians and their immediate family members. Effective January 1, 2022, applicable manufacturers are required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and,
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; state, local and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, obtain pharmaceutical agent licensure, and/or otherwise restrict payments that may be made to healthcare providers and entities; and state, local and foreign laws and industry codes that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or entities, or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Moreover, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal health care fraud statutes, so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may

assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Recently, several pharmaceutical and other healthcare companies have been prosecuted under the federal false claims laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, interactions with specialty pharmacies, and patient assistance programs may also violate fraud and abuse laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations.

In addition, certain state and local laws mandate that we comply with a state code of conduct, adopt a company code of conduct under state criteria, disclose marketing payments made to health care professionals and entities, disclose drug pricing information and/or report compliance information to the state authorities. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and reporting requirements increase the possibility that a pharmaceutical company may violate one or more of the requirements. Any failure to comply with these reporting requirements could result in significant fines and penalties.

The risks of complying with these laws cannot be entirely eliminated. The risk of violation of such laws is also increased because many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state, local and foreign privacy, security, fraud and transparency laws may prove costly. If our past or present operations, or those of our distributors are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to sanctions, including civil and administrative penalties, criminal fines, damages, disgorgement, exclusion from participation in U.S. federal or state health care programs, individual imprisonment, integrity obligations, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Similarly, if healthcare providers, distributors or other entities with whom we do business are found to be out of compliance with applicable laws and regulations, they may be subject to sanctions, which could also have a negative impact on us.

Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations or applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. Further, due to the risk that a judgment in a False Claims Act case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

Our operations, including our use of hazardous materials, chemicals, bacteria, and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

EU Member States, Switzerland and other countries have adopted data protection laws and regulations, which impose significant compliance obligations. For example, European Union, or EU, member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the EU is now governed under the EU General Data Protection Regulation, or the GDPR, effective in May 2018. The GDPR, which is wide-ranging in scope, imposed several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. The GDPR increases our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. However, despite our ongoing efforts, we may not be successful either due to various factors within our control, such as limited financial or human resources, or other factors outside our control. It is also possible that local data protection authorities may have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures, or measures relating to privacy, data security, marketing, or communications) by us to comply with laws, regulations, policies, legal or contractual obligations, industry standards, or regulatory guidance relating to privacy or data security, may result in governmental investigations and enforcement actions, litigation, fines and penalties or adverse publicity. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States, and we cannot determine the impact such future laws, regulations and standards may have on our business.

If we experience a significant disruption in our information technology systems or breaches of data security, including due to a cybersecurity incident, our business could be adversely affected.

We rely on information technology systems to keep financial records, capture laboratory data, maintain clinical trial data and corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events including but not limited to natural disaster.

We also face the challenge of promptly detecting and remediating any cybersecurity breaches. Our information technology systems security measures are focused on the prevention, detection and remediation of damage from computer viruses, unauthorized access, cyber-attack and other similar disruptions. However, our information technology systems protection measures may not be successful in preventing unauthorized access, intrusion and damage. Threats to our systems can derive from human error, fraud or malice on the part of employees or third parties, including computer hackers, encryption by ransomware, or may result from technological failure.

If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could delay or negatively impact our development and commercialization of our product candidates, which could adversely impact our business. If operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe.

In addition, as discussed above, our information technology systems are potentially vulnerable to data security breaches—whether by employees or others, intentionally or unintentionally—which may expose sensitive or personal data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, customers and others, any of which could have a material adverse effect on our business, financial condition and results of operations.

Moreover, a security breach or privacy violation that leads to destruction, loss, alteration, unauthorized use or access, disclosure or modification of, personally identifiable information or personal data, could harm our reputation, compel us to comply with federal, state and/or international breach notification laws, subject us to mandatory corrective or regulatory action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, including the GDPR and the California Consumer Privacy Act of 2018, which could disrupt our business, result in increased costs or loss, and/or result in significant legal and financial exposure. In addition, a data security breach could result in loss of clinical trial data or damage to the integrity of that data.

If we are unable to implement and maintain adequate organizational and technical measures to prevent such security breaches or privacy violations, or to respond adequately in the event of a breach, our operations could be disrupted, and we may suffer loss of reputation, problems with regulatory authorities, financial loss and other negative consequences. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

If a breach of our information technology systems or those of our key third-party vendors occurs, we may incur additional costs related to repairing or rebuilding our internal systems, complying with breach notification laws, defending legal claims or proceedings, responding to regulatory actions, incurring penalties, and paying damages. Moreover, it may be determined that as a result of such a breach there was a material weakness or significant deficiency in our internal controls or other failure of our control environment. If such a breach occurs, it may have a material adverse effect on our business, results of operations, and financial condition, and it may also negatively impact our reputation.

Intellectual Property Risks

If we are unable to protect our intellectual proprietary rights, our business could be harmed.

Our commercial success will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology, products and product candidates. Obtaining and maintaining this protection is very costly. The patentability of technology in the biotechnology field generally is highly uncertain and involves complex legal and scientific questions. We cannot be certain that our patents and patent applications, including our own and those that we have rights through licenses from third parties, will adequately protect our intellectual property. Our success in protecting our intellectual property depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents, that are meaningful to our products, including defending those patents against adverse claims;
- secure patent term extension for the patents covering our approved products;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and,
- prevent others from infringing our proprietary rights.

We may not be able to obtain issued patents relating to our technology or product candidates. Even if issued, patents may inadvertently lapse or be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our product candidates. Further, patents may lapse prior to the regulatory approval of the underlying product in one or more territories. In the past, we have abandoned the prosecution and/or maintenance of patent applications related to patent families in the ordinary course of business. In the future, we may choose to abandon such prosecution and/or maintenance in a similar fashion. If these patent rights are later determined to be valuable or necessary to our business, our competitive position may be adversely affected. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and in other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defensive measures.

Patent and other intellectual property laws outside the United States are even more uncertain than in the United States and are continually undergoing review and revisions in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, certain countries do not grant patent claims that are directed to business methods and processes. In addition, we may have to participate in additional opposition proceedings, like the proceedings described above, to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts.

Our collaborative partners and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend intellectual property rights in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties.

The cost of litigation to uphold the validity of patents, once obtained, to prevent infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subject to patent office proceedings. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume management's time and attention and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions covered by or incorporating them. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on

the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially and adversely affected.

In addition to patent litigation, we may be a party to adversarial proceedings before the Patent Trial and Appeal Board (PTAB) of the USPTO, or the Opposition Divisions of the European Patent Office (EPO). Potential proceedings before the PTAB include inter parties review proceedings, post-grant review proceedings and interference proceedings. Depending on our level of success at the PTAB and Opposition Divisions of the EPO, these proceedings could adversely impact our intellectual property rights with respect to our products and technology.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Patent and intellectual property laws outside of the United States may also change and be uncertain.

Our patents, once obtained, also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We also will rely on current and future trademarks to establish and maintain recognized brands, including APTEVO THERAPEUTICS, APTEVO BIOTHERAPEUTICS, APTEVO RESEARCH AND DEVELOPMENT, the Aptevio logo, ADAPTIR, and ADAPTIR-FLEX in relevant jurisdictions. If we fail to acquire and protect such trademarks, our ability to market and sell our products, if approved for marketing, will be harmed. In addition, our current and future trademarks may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks and we may not be able to protect our rights in these trademarks, which we need in order to build name recognition. Any of the foregoing could have a material and adverse effect on our business, financial condition and operating results.

If approved, our products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation.

There is a similar abbreviated pathway for the approval of biosimilar products in the EU. Reference products in the EU benefit from an eight-year data exclusivity period during which the data included in the dossier for the reference product may not be referenced for the purposes of an abbreviated biosimilar application. Following the expiration of the data exclusivity period, there is an additional two-year period of market exclusivity during which a biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no product can be placed on the market until the expiration of such period. The overall 10-year period can be extended to a maximum of 11 years in certain circumstances. As in the U.S., there is no guarantee that a product will qualify for the prescribed period of exclusivity and, even if a product does qualify, another company may market a competing version of the reference product if such company obtained a marketing authorization with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing any of our products, if approved, our products may become subject to competition from such biosimilars, which would impair our ability to successfully commercialize and generate revenues from sales of such products.

Third parties may choose to file patent infringement claims against us.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold sufficient licenses or other rights. Third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. These third parties may have substantially greater financial resources than us and could bring claims against us that could cause us to incur substantial expenses to defend against these claims and, if successful against us, could cause us to pay substantial damages. If a patent infringement or other similar suit were brought against us, we could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the biotechnology industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we may choose or be required to seek a license from the third-party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, if at all, or if an injunction is granted against us, which could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other adversarial proceedings such as proceedings before the Patent Trial Appeals Board and opposition proceedings in the European Patent Office, regarding intellectual property rights that could impact our products and technology.

Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting

from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Our Apteva trademarks may be opposed which could have a material and adverse effect on our business.

We have an application pending that covers the APTEVO THERAPEUTICS trademark and received a notice of allowance in September 2022 from the USPTO for the APTEVO BIOTHERAPEUTICS and APTEVO RESEARCH AND DEVELOPMENT trademarks. We refer to these trademarks as our house marks. If a third-party opposes any of these house marks and we are unable to reach settlement prior to the commencement of an opposition proceeding, we may incur significant expense in the course of participating in the opposition process, which can be expensive and lengthy. Any settlement with a third-party may result in our agreeing to be subject to restrictions on our use of the relevant house mark. In addition, if we are unsuccessful in an opposition against a house mark, we would lose the ability to obtain trademark registration for one or more uses of the relevant mark both in the United States and in other territories which could have a material and adverse effect on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Failure to comply with our obligations in our intellectual property licenses with third parties, could result in loss of license rights or other damages.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license in whole or in part, terminate the exclusive nature of the license and/or sue us for breach, which could cause us to not be able to market any product that is covered by the licensed patents and may be subject to damages.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and product candidates could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, information processes and know-how. These types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants and third parties as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known, including through a potential cyber security breach, or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

Risks Related to Collaborations and Other Transactions

We may not be successful in establishing and maintaining collaborations and entering into other transactions that leverage our capabilities in pursuit of developing and commercializing our product candidates and any such collaborations and transactions, if any, could result in financial results that differ from market expectations.

For each of our product candidates we plan to evaluate the merits of entering into collaboration arrangements with third parties, including leading biotechnology companies or non-governmental organizations. In July 2017, we entered into a collaboration agreement with Alligator pursuant to which Aptevo R&D and Alligator have been collaboratively developing ALG-APV-527, a first-in-class bispecific antibody candidate simultaneously targeting 4-1BB (CD137), a member of the TNFR superfamily of a co-stimulatory receptor found on activated T-cells, and 5T4, a tumor antigen widely overexpressed in a number of different types of cancer. We intend to pursue collaboration arrangements with third parties that have particular technology, expertise or resources for the development or commercialization of our product candidates or for accessing particular markets. We face, and will continue to face, significant competition in seeking appropriate partners for our product candidates. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on a timely basis, on acceptable terms or at all, or if the arrangements we establish are unproductive for us, we may fail to meet our business objectives for the particular product candidate. Our ability to enter into such arrangements with respect to products in development that are subject to licenses may be limited by the terms of those licenses.

Our collaboration agreement with Alligator, or any collaboration agreement we may consider entering into, may not be successful and the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborative partners. It is likely that our collaborative partners will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

The risks that we are subject to in any of our collaborations include, among others:

- our collaborative partners may not commit adequate resources to the development, marketing and distribution of any collaboration products, limiting our potential revenues from these products;
- our collaborative partners may experience financial difficulties and may therefore be unable to meet their commitments to us;
- our collaborative partners may pursue a competing product candidate developed either independently or in collaboration with others, including our competitors; and,
- our collaborative partners may terminate our relationship.

The failure of any of our current or future collaboration partners to perform as expected could place us at a competitive disadvantage and adversely affect us financially, including delay and increased costs of development, loss of market opportunities, lower than expected revenues and impairment of the value of the related product candidate. A loss of our collaboration agreement with Alligator would result in a burden of locating a replacement partner under potentially less favorable terms at an additional cost. Collaborations are a critical part of our business strategy, and any inability on our part to establish and successfully maintain such arrangements on terms favorable to us or to work successfully with our collaborative partners could have an adverse effect on our operations and financial performance. Due to the macroeconomic factors, we may experience delays in opportunities to develop our product candidates, due to financial and other impacts on potential partners.

In addition, in the normal course of business, the Company engages in discussions with third parties regarding possible strategic alliances, joint ventures, acquisitions, divestitures and business combinations to further develop or commercialize our product candidates. As a result of such transactions, our financial results may differ from our own or the investment community's expectations in a given fiscal quarter or over the long term. Furthermore, efforts to engage in such transactions require varying levels of management resources, which may divert the Company's attention from other business operations. Any transactions we engage in could result in our financial results differing materially from market expectations.

Risks Related to Our Common Stock and General Risks

Our stock price is and may continue to be volatile.

Our stock price has fluctuated in the past and is likely to be volatile in the future. Between August 1, 2016 and September 30, 2024, the reported closing price of our common stock has fluctuated between \$0.165 and \$3,659.04 per share (as adjusted to reflect our 1-for-44 reverse stock split of our outstanding common stock that was effective on March 5, 2024). The stock market in general, and the market for biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In particular, the stock market has experienced extreme volatility in recent months as a result of the geopolitical tension or political events, including the impact from the United States presidential election and congressional elections, the war in Ukraine and the rising conflict in the Middle East, and macroeconomic conditions, including rising and fluctuating inflation

and interest rates and reduced consumer confidence. The market price of our common stock may fluctuate significantly due to a number of factors, some of which may be beyond our control or unrelated to our operations, including, among others:

- investor perceptions or negative announcements by our competitors, suppliers, or partners regarding their own performance;
- the success of competitive products or technologies;
- the timing, expenses, and results of clinical and preclinical trials of our product candidates;
- announcements regarding clinical trial results and product introductions by us or our competitors;
- announcements of acquisitions, collaborations, financings or other transactions by us or our competitors;
- public concern as to the safety of our product candidates;
- termination or delay of a development program;
- the recruitment or departure of key personnel;
- estimated or actual sales of IXINITY by Medexus;
- actual or anticipated variations in our cash flows or results of operations;
- the operating and stock price performance of comparable companies;
- general industry and macroeconomic conditions, including domestic and global financial, economic, and geopolitical instability;
- changes in earnings estimated by securities analysts or management, or our ability to meet those estimates;
- technical factors in the public trading market for our stock that may produce price movements that may or may not comport with macro, industry or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as may be expressed on financial trading and other social media sites) and the amount and status of short interest in our common stock;
- our ability to continue as a going concern; and
- the other factors described in this "Risk Factors" section.

Biotechnology company stock prices have declined significantly in certain instances where companies have failed to obtain FDA or foreign regulatory authority approval of a product candidate or if the timing of FDA or foreign regulatory authority approval is delayed. If the FDA's or any foreign regulatory authority's response to any application for approval is delayed or not favorable for any of our product candidates, our stock price could decline significantly.

In addition, when the market price of a company's common stock drops significantly, stockholders often institute securities class action lawsuits against the company. A lawsuit against us could cause us to incur substantial costs and could divert the time and attention of our management and other resources.

We have in the past and may in the future be subject to short selling strategies that may drive down the market price of our common stock.

Short sellers have in the past and may attempt in the future to drive down the market price of our common stock. Short selling is the practice of selling securities that the seller does not own but may have borrowed with the intention of buying identical securities back at a later date. The short seller hopes to profit from a decline in the value of the securities between the time the securities are borrowed and the time they are replaced. As it is in the short seller's best interests for the price of the stock to decline, many short sellers (sometime known as "disclosed shorts") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by weblog ("blogging") have allowed many disclosed shorts to publicly attack a company's credibility, strategy and veracity by means of so-called "research reports" that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short attacks have, in the past, led to selling of shares in the market. Further, these short seller publications are not regulated by any governmental, self-regulatory organization or other official authority in the U.S. and they are not subject to certification requirements imposed by the SEC. Accordingly, the opinions they express may be based on distortions, omissions or fabrications. Companies that are subject to unfavorable allegations, even if untrue, may have to expend a significant amount of resources to investigate such allegations and/or defend themselves, including shareholder suits against

the company that may be prompted by such allegations. We may in the future be the subject of shareholder suits that we believe were prompted by allegations made by short sellers.

In the event that coverage under our directors' and officers' liability insurance is reduced or terminated as a result of an ownership change or otherwise, our indemnification obligations and limitations of our directors' and officers' liability insurance may have a material adverse effect on our financial condition, results of operations and cash flows.

Under Delaware law, our certificate of incorporation, and our by-laws and certain indemnification agreements to which we are a party, we have an obligation to indemnify, or we have otherwise agreed to indemnify, certain of our current and former directors and officers with respect to past, current, and future investigations and litigation. In order to reduce the risk of expense of these obligations, we maintain directors' and officers' liability insurance. A significant change in the Company's risk profile could increase the cost to us of our directors' and officers' liability insurance coverage or the coverage thereunder may be reduced or terminated in full. In the event that the coverage under our directors' and officers' liability insurance is reduced or terminated, we will be required to pay the expenses of indemnifying our current and former directors and officers in their defense of current and future investigations and litigation, which expenses may be significant. The increased costs to us of our directors' and officers' liability insurance coverage, or our indemnification obligations if our directors' and officers' liability insurance coverage is reduced or terminated, could result in the diversion of our financial resources, and may have a material adverse effect on our financial condition, results of operations and cash flows.

If we do not maintain effective internal controls, we may not be able to accurately report our financial results and our business could be harmed.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404 of the Sarbanes-Oxley Act, or Section 404, requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. In the past, we were an emerging growth company and we currently are a non-accelerated filer and have availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. If we cease to be a non-accelerated filer and our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Investor perceptions of our company may suffer if material weaknesses are found, and this could cause a decline in the market price of our common stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could harm our operating results and reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

The public announcement of data from clinical trials or news of any developments related to our product pipeline may cause significant volatility in our stock price.

The announcement of data from clinical trials by us or our collaborative partners or news of any developments related to our key pipeline product candidates has in the past caused and may in the future cause significant volatility in our stock price. Furthermore, the announcement of any negative or unexpected data or the discontinuation of development of any of our key pipeline product candidates, or any delay in our anticipated timelines for filing for regulatory approval, could cause our stock price to decline significantly. There can be no assurance that data from clinical trials will support a filing for regulatory approval or even if approved, that any of our key pipeline products will become commercially successful.

Our common stock may be at risk for delisting from the Nasdaq Capital Market in the future if we do not maintain compliance with Nasdaq's continued listing requirements. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is currently listed on the Nasdaq Capital Market LLC ("Nasdaq"). Nasdaq has minimum requirements that a company must meet in order to remain listed on Nasdaq, including corporate governance standards and a requirement that we maintain a minimum closing bid price of \$1.00 per share and a minimum stockholders' equity of at least \$2.5 million, among other requirements.

On June 25, 2024, the Company received a letter from Nasdaq notifying the Company that, for the last 30 consecutive business days, the bid price of the Company's common stock had closed below \$1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement").

Nasdaq's letter has no immediate impact on the listing of the Company's common stock, which will continue to be listed and traded on Nasdaq, subject to the Company's compliance with the other continued listing requirements. Nasdaq's letter provides the Company 180 calendar days, or until December 23, 2024 (the "Compliance Date"), to regain compliance with the Bid Price Requirement. To regain compliance with the Bid Price Requirement, the closing bid price of the Company's common stock must be at least \$1.00 per share for a minimum of ten consecutive business days before the Compliance Date. The Company may be eligible for an additional 180-day period to regain compliance if the Company meets all other listing standards of Nasdaq, with the exception of the Bid Price Requirement, and provides written notice to Nasdaq of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. In the event the Company fails to regain compliance, the Company would have the right to a hearing before the Nasdaq Listing Qualifications Panel (the "Panel"). There can be no assurance that, if the Company receives a delisting notice and appeals the delisting determination by the Panel, such appeal would be successful.

The Company intends to take all reasonable measures available to regain compliance under the Nasdaq Listing Rules and remain listed on Nasdaq, including by effecting a reverse stock split.

In the future, if we fail to maintain such minimum requirements and a final determination is made by Nasdaq that our common stock must be delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease. In addition, if delisted, we would no longer be subject to Nasdaq rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards. Our failure to be listed on Nasdaq or another established securities market would have a material adverse effect on the value of your investment in us.

If our common stock is not listed on Nasdaq or another national exchange, the trading price of our common stock is below \$5.00 per share and we have net tangible assets of \$6,000,000 or less, the open-market trading of our common stock will be subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended. If our shares become subject to the "penny stock" rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected.

Your percentage of ownership in Apteva may be diluted in the future.

In the future, your percentage ownership in Apteva may be diluted because of equity issuances or securities convertible into equity for acquisitions, capital market transactions or otherwise, including, but not limited to, equity issuances under our Rights Agreement with Broadridge Corporate Issuer Solutions, Inc., upon the exercise of warrants issued in connection with both of our 2023 and 2024 registered offerings and equity awards to our directors, officers and employees. Our employees have options to purchase shares of our common stock and from time to time, we expect to issue additional options, restricted stock units, or other stock-based awards to our employees under our employee benefits plans.

In addition, our restated certificate of incorporation authorizes us to issue, without the approval of our stockholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our common stock respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, we could grant the holders of preferred stock the right to elect some number of our directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock.

Provisions under Delaware law and in our restated certificate of incorporation, amended and restated by-laws and rights agreement may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

Certain provisions in our restated certificate of incorporation and amended and restated by-laws, and under Delaware law, may discourage, delay, or prevent a merger, acquisition or other changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our incumbent directors and management.

These provisions include:

- the classification of our directors;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;

- advance notice requirements for stockholder nominations of candidates for election to the Board of Directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and,
- the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

The affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. The affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, Section 203 of the General Corporation Law of Delaware prohibits a corporation from engaging in a business combination with an interested stockholder, generally a person which, together with its affiliates, owns or within the last three years has owned 15% or more of the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

Moreover, we currently have a short-term stockholder Rights Agreement in effect. On November 1, 2024, we entered into amendment No. 4 to the Rights Agreement and extended the expiration of such agreement to October 31, 2025. This Rights Agreement could render more difficult, or discourage a merger, tender offer, or assumption of control of the Company that is not approved by our Board that some stockholders may consider favorable. The Rights Agreement, however, should not interfere with any merger, tender or exchange offer or other business combination approved by our Board. Nor does the Rights Agreement prevent our Board from considering any offer that it considers to be in the best interest of our stockholders.

Our by-laws include a forum selection clause, which may impact your ability to bring actions against us.

Subject to certain limitations, our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware will be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring: (a) any derivative action or proceeding brought on our behalf; (b) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees or our stockholders; (c) any action asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or by-laws; or (d) any action asserting a claim governed by the internal affairs doctrine. In addition, our bylaws provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the federal securities laws of the United States against us, our officers, directors, employees or underwriters. These limitations on the forum in which stockholders may initiate action against us could create costs, inconvenience or otherwise adversely affect your ability to seek legal redress.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, a court may decline to enforce these exclusive forum provisions with respect to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction, and our stockholders may not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find the exclusive forum provisions to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

We may be subject to periodic litigation, which could result in losses or unexpected expenditure of time and resources.

From time to time, we may be called upon to defend ourselves against lawsuits relating to our business. Any litigation, regardless of its merits, could result in substantial costs and a diversion of management's attention and resources that are needed to successfully run our business. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of any such proceedings. An unfavorable outcome in any such proceedings could have an adverse impact on our business, financial condition and results of operations. If our stock price is volatile, we may become involved in securities class action lawsuits in the future.

A significant portion of our shares may be sold into the market at any time which could depress our stock price.

If our stockholders sell a substantial number of shares of our common stock in the public market, our market price could decline. Any such sales or perception that such sales may occur could decrease the market price of our common stock.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

In the quarter ended September 30, 2024, none of our directors or executive officers adopted, terminated or materially modified a plan for the purchase or sale of our securities intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or a non-Rule 10b5-1 trading arrangement for the purchase or sale of our securities, within the meaning of Item 408 of Regulation S-K.

Item 6. Exhibits

Exhibit Index

Exhibit Number	Description
4.1	Common Warrant, dated September 18, 2024, filed as Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
4.2	Pre-Funded Warrant, dated September 18, 2024, filed as Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
4.3	Amendment No. 4 to Rights Agreement, dated as of November 1, 2024, between the Company and Broadridge Corporate Issuer Solutions, Inc., as Rights Agent, filed as Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on November 4, 2024 and incorporated herein by reference.
10.1	Placement Agency Agreement dated September 16, 2024, between the Company and Roth Capital Partners, filed as Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
10.2	Securities Purchase Agreement, dated September 16, 2024, between the Company and the purchasers party thereto, filed as Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
10.3	Form of Amended Series A-1 Common Warrant, dated September 18, 2024 (originally entered into on November 9, 2023), between the Company and certain warrant holders, filed as Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
10.4	Form of Amended Series A-2 Common Warrant, dated September 18, 2024 (originally entered into on November 9, 2023), between the Company and certain warrant holders, filed as Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
10.5	Form of Amended Series B-1 Common Warrant, dated September 18, 2024 (originally entered into on November 9, 2023), between the Company and certain warrant holders, filed as Exhibit 10.5 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
10.6	Form of Amended Series B-2 Common Warrant, dated September 18, 2024 (originally entered into on November 9, 2023), between the Company and certain warrant holders, filed as Exhibit 10.6 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
10.7	Form of Amended Warrant, dated September 18, 2024 (originally entered into on April 15, 2024), between the Company and certain warrant holders, filed as Exhibit 10.7 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
10.8	Form of Amended Warrant, dated September 18, 2024 (originally entered into on July 1, 2024), between the Company and certain warrant holders, filed as Exhibit 10.8 to the Current Report on Form 8-K filed with the SEC on September 18, 2024 and incorporated herein by reference.
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.

Exhibit Number	Description
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.INS*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)
* Filed herewith.	
** Furnished herewith.	

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.

APTEVO THERAPEUTICS INC.

Date: November 7, 2024

By: /s/ Marvin L. White

Marvin L. White
President and Chief Executive Officer

Date: November 7, 2024

By: /s/ Daphne Taylor

Daphne Taylor
Senior Vice President and Chief Financial Officer

**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, Marvin White, certify that:

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

Date: November 7, 2024

By:

/s/ Marvin L. White
Marvin L. White
President and Chief Executive Officer

**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, Daphne Taylor, certify that:

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

Date: November 7, 2024

By:

/s/ Daphne Taylor
Daphne Taylor
Senior Vice President and Chief Financial Officer

**CERTIFICATION PURSUANT TO
RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AND
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 Apteva Therapeutics Inc. on Form 10-Q for the period ending September 30, 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:

- (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 result of operations of the Company.

Date: November 7, 2024

By:

/s/ Marvin L. White

Marvin L. White

President and Chief Executive Officer

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

**CERTIFICATION PURSUANT TO
RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AND
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 Apteko Inc. on Form 10-Q for the period ending September 30, 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:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 7, 2024

By: */s/ Daphne Taylor***Daphne Taylor****Senior Vice President and Chief Financial Officer**

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