UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-42001

Contineum Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**27-1467257**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10578 Science Center Drive, Suite 200 San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 333-5280
(Registrant's telephone number, including area code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, $0.001 par value per share	**CTNM**	**The Nasdaq Stock Market LLC (Nasdaq Global Select Market)**

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of May 15, 2024, the registrant had 18,994,104 shares of Class A common stock, $0.001 par value per share, outstanding and 6,729,172 shares of Class B common stock, $0.001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these terms or other similar expressions are intended to identify forward looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- the likelihood of our clinical trials demonstrating the safety and efficacy of our drug candidates;
- the timing and progress of our current clinical trials, the expected results of these clinical trials and the timing of initiation of our future clinical trials;
- our plans relating to the clinical development of our current and future drug candidates, including the size, number and disease areas to be evaluated;
- Johnson & Johnson's ("J&J") plans related to the clinical development of PIPE-307;
- our clinical translational approach, and our ability to identify and develop drug candidates that can potentially treat neuroscience, inflammation and immunology ("NI&I") diseases by targeting biological pathways associated with specific clinical impairment to alter the course of disease;
- the size of the market opportunities for our drug candidates;
- the rate and degree of market acceptance and clinical utility of our drug candidates;
- our plans relating to commercializing our drug candidates, if approved;
- the success of competing therapies and technologies that are or may become available;
- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our drug candidates;
- the timing or likelihood of regulatory filings and approval for our drug candidates;
- our ability to obtain and maintain regulatory approval of our drug candidates and our drug candidates to meet existing or future regulatory standards;
- our plans relating to the further development and manufacturing of our drug candidates, including additional indications for which we may pursue;
- our ability to successfully identify and complete transactions to in-license or otherwise acquire additional drug candidates, technologies, products or businesses;
- our ability to attract and to enter into commercial arrangements with third parties who have development, regulatory, manufacturing and commercialization expertise;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available, as well as our ability to secure and maintain intellectual property regulatory rights and regulatory protections;
- our ability to retain our senior management;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;

• the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;

• the period during which we expect we will qualify as an emerging growth company under the JOBS Act or a smaller reporting company;

• our anticipated use of our existing cash, cash equivalents and marketable securities; and

• other risks and uncertainties, including those described under Part II, Item 1A, “Risk Factors” of this Quarterly Report on Form 10-Q.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A, “Risk Factors” of this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements or rely on forward-looking statements as predictions of future events. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context otherwise indicates, references in this Quarterly Report on Form 10-Q to the terms, “Contineum,” the "Company," “we,” “our,” and “us” refer to Contineum Therapeutics, Inc. and references to our “common stock” refer to our voting Class A common stock.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to a number of risks that if realized could materially affect our business, prospects, operating results and financial condition. Below is a summary of the risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, are set forth under Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q. Some of the material risks associated with our business include the following:

• We are heavily dependent on the success of PIPE-791, our lead drug candidate, and PIPE-307, both of which are in the early stages of clinical development. If these drug candidates do not progress through clinical development, eventually receive regulatory approval or, even if approved, are not successfully commercialized, our business will be materially adversely harmed.

• Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes. The results of earlier preclinical studies and clinical trials, including those conducted by third parties, may not be predictive of future results. If clinical trials for the drug candidates we develop do not meet safety or efficacy endpoints or are prolonged or delayed, these drug candidates may not receive the required regulatory approvals, and therefore could not be commercialized on a timely basis or at all. Further, the results of our preclinical studies, clinical trials, or analyses may not be indicative of results that may be obtained in later trials.

• The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory authorities are unpredictable, lengthy, and time-consuming, and if we are ultimately unable to obtain regulatory approval for PIPE-791 or any other drug candidates that we develop or J&J is unable to obtain regulatory approval for PIPE-307, our business will be substantially harmed.

•We may not be successful in our efforts to identify and develop additional drug candidates or identify additional indications. Due to our limited resources and access to capital, we must prioritize development of a limited number of drug candidates, the choice of which may prove to be wrong and adversely affect our business.

•We have and may continue to conduct future clinical trials outside of the United States. The FDA and other regulatory authorities or ethics committees may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business and financial condition.

•We have incurred significant operating expenses since inception and anticipate that our operating expenses will continue to significantly increase for the foreseeable future. As a result, we may be unable to sustain profitability, and if we are unable to achieve sustained profitability, the market value of our common stock will likely decline. As of March 31, 2024, we had an accumulated deficit of $83.6 million.

•We have a limited operating history and the drug candidates we have developed are in the early stages of clinical development, which may make it difficult to evaluate the prospects for our future viability.

•We will require significant additional capital to complete the development and commercialization of PIPE-791 and the other drug candidates we select for development.

•If the license agreement we entered into with Johnson & Johnson Innovative Medicine (formerly Janssen Pharmaceutica NV), an affiliate of J&J (collectively referred to herein with J&J as "J&J") in which we granted J&J an exclusive, worldwide license to develop, manufacture and commercialize PIPE-307 in all indications (the "J&J License Agreement") does not result in the successful development of PIPE-307, our business, financial condition and results of operations will be harmed.

•We may seek to grow our business through in-licensing transactions or otherwise by acquiring drug candidates or complementary products, technologies or businesses. The failure to properly identify these drug candidates, products, technologies or businesses, as well as the failure to successfully complete transactions or to integrate any such drug candidates, products, technologies or businesses that we do in-license or acquire with our existing business, could harm our business, financial condition and operating results.

•If we are unable to obtain, maintain and enforce intellectual property protection for our technology and drug candidates or if the scope of the intellectual property protection we obtain is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize and generate revenues from our drug candidates may be adversely affected.

•We currently rely on third-party contract manufacturing organizations ("CMOs") for the production of clinical supplies of PIPE-791 and PIPE-307 and we intend to rely on CMOs for our future drug candidates, as well as to supply the raw materials necessary to produce our drug candidates. We may elect to continue to rely on CMOs for the production of commercial supplies of PIPE-791, if approved. Our dependence on CMOs may impair our development of drug candidates and may impair their commercialization, which would adversely impact our business and financial position.

•We rely on third parties to conduct our ongoing clinical trials of PIPE-791 and PIPE-307 and expect to rely on third parties to conduct future clinical trials of PIPE-791 and any other drug candidates that we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize the drug candidates we develop and our business could be substantially harmed.

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

•We face significant competition from biotechnology, pharmaceutical, and medical device companies, and our operating results will suffer if we fail to compete effectively and in a timely manner.

•Even if PIPE-791 or PIPE-307 receives marketing approval in an indication, it may fail to achieve market acceptance by physicians, patients, third-party payors, or others in the medical community necessary for commercial success.

•We have no sales, marketing or distribution capabilities or experience. If we are unable to establish sales and marketing capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing PIPE-791, even if approved.

•Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

CONTINEUM THERAPEUTICS, INC.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CONTINEUM THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(unaudited)
(in thousands, except share and par value data)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 16,264	$ 15,526
Marketable securities	101,643	109,664
Prepaid expenses and other current assets	1,804	2,516
Total current assets	119,711	127,706
Property and equipment, net	756	678
Other long-term assets	2,623	1,283
Operating lease right-of-use assets	474	719
Total assets	$ 123,564	$ 130,386
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 570	$ 635
Accrued expenses	5,190	4,385
Current portion of operating lease liabilities	474	464
Total current liabilities	6,234	5,484
Other long-term liabilities	228	110
Operating lease liabilities, net of current portion	111	108
Total liabilities	6,573	5,702
Convertible preferred stock, $0.001 par value; authorized shares— 16,940,594 at March 31, 2024 and December 31, 2023; issued shares and outstanding shares— 15,906,236 at March 31, 2024 and December 31, 2023; $193,462 aggregate liquidation preference at March 31, 2024	192,620	192,620
Stockholders' deficit:		
Common stock, $0.001 par value; authorized shares—39,630,511 at March 31, 2024 and December 31, 2023, respectively; issued shares—2,384,426 and 2,349,554 at March 31, 2024 and December 31, 2023 respectively; outstanding shares—2,384,426 and 2,349,554 at March 31, 2024 and December 31, 2023 respectively.	2	2
Additional paid-in-capital	7,988	7,098
Accumulated deficit	(83,561)	(75,144)
Accumulated other comprehensive income (loss)	(58)	108
Total stockholders' deficit	(75,629)	(67,936)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 123,564	$ 130,386

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

CONTINEUM THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 7,778	$ 3,632
General and administrative	2,152	1,483
Total operating expenses	9,930	5,115
Loss from operations	(9,930)	(5,115)
Other income (expense):		
Interest income	1,636	401
Interest expense	—	(92)
Change in fair value of preferred stock warrant liability	(117)	—
Other expense, net	(6)	(18)
Total other income	1,513	291
Loss before income taxes	(8,417)	(4,824)
Provision for income taxes	—	—
Net loss	(8,417)	(4,824)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	(166)	67
Comprehensive loss	$ (8,583)	$ (4,757)
Net loss per share, basic and diluted	$ (3.55)	$ (2.12)
Weighted average shares of common stock outstanding, basic and diluted	2,369,067	2,277,555

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

CONTINEUM THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	15,906,236	$ 192,620	2,349,554	$ 2	$ 7,098	$ 108	$ (75,144)	$ (67,936)
Exercise of stock options	—	—	34,872	—	122	—	—	122
Stock-based compensation expense	—	—	—	—	768	—	—	768
Net loss	—	—	—	—	—	—	(8,417)	(8,417)
Unrealized loss on marketable securities	—	—	—	—	—	(166)	—	(166)
Balance at March 31, 2024	15,906,236	$ 192,620	2,384,426	$ 2	$ 7,988	$ (58)	$ (83,561)	$ (75,629)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	11,889,674	$ 132,482	2,259,734	$ 2	$ 4,726	$ (76)	$ (97,864)	$ (93,212)
Vesting of shares of common stock subject to repurchase	—	—	5,245	—	5	—	—	5
Exercise of stock options	—	—	7,146	—	8	—	—	8
Stock-based compensation expense	—	—	—	—	494	—	—	494
Net loss	—	—	—	—	—	—	(4,824)	(4,824)
Unrealized gain on marketable securities	—	—	—	—	—	67	—	67
Balance at March 31, 2023	11,889,674	$ 132,482	2,272,126	$ 2	$ 5,233	$ (9)	$ (102,688)	$ (97,462)

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

CONTINEUM THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2024	**2023**
Operating activities		
Net loss	$ (8,417)	$ (4,824)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	61	73
Non-cash operating lease expense	244	238
Stock-based compensation	768	494
Amortization of debt discount and debt issuance costs	—	26
Accretion of premiums/discounts on investments, net	(1,023)	(261)
Change in fair value of preferred stock warrant liability	117	—
Gain on marketable securities	—	24
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	713	(60)
Other long-term assets	—	5
Accounts payable	(70)	282
Accrued expenses	(380)	(978)
Operating lease liabilities	12	(263)
Net cash used in operating activities	(7,975)	(5,244)
Investing activities		
Purchase of property and equipment	(147)	(52)
Purchases of marketable securities	(30,640)	(9,216)
Sales and maturities of marketable securities	39,518	18,623
Net cash provided by investing activities	8,731	9,355
Financing activities		
Payments of deferred offering costs	(140)	—
Principal payments on debt	—	(625)
Proceeds from exercise of stock options	122	8
Net cash used in financing activities	(18)	(617)
Net increase in cash and cash equivalents	738	3,494
Cash and cash equivalents at beginning of period	15,526	5,569
Cash and cash equivalents at end of period	$ 16,264	$ 9,063

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

CONTINEUM THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

Organization and Nature of Operations

Contineum Therapeutics, Inc. (the "Company"), is a clinical stage biopharmaceutical company focused on discovering and developing novel, oral small molecule therapies for neuroscience, inflammation and immunology indications with high unmet need. The Company, formerly named Sirocco Therapeutics, Inc. ("Sirocco" or "legacy Sirocco"), Inception 3, Inc. ("Inception") and Versense Pharmaceuticals, Inc. ("Versense"), was incorporated in the state of Delaware in 2009 as Versense. Versense changed its name to Inception on October 25, 2011, and commenced active operations on July 13, 2012. In May 2018, Inception changed its name to Sirocco. A separate entity named Pipeline Therapeutics, Inc. ("legacy Pipeline") was founded and incorporated in the state of Delaware on May 9, 2017. On May 7, 2019, legacy Sirocco acquired legacy Pipeline in a merger transaction (the "Merger"). As of December 31, 2019, legacy Pipeline was a wholly owned subsidiary of legacy Sirocco. In January 2020, legacy Pipeline was merged into legacy Sirocco and ceased to exist, and legacy Sirocco changed its name to Pipeline Therapeutics, Inc. In November 2023, Pipeline Therapeutics, Inc. changed its name to Contineum Therapeutics, Inc.

Reverse Stock Split

On April 1, 2024, the Company filed an amendment to its fourth amended and restated certificate of incorporation as amended and effected a 1-for-5.5972 reverse stock split of its capital stock. All share and per-share amounts presented in the financial statements and related notes have been retroactively adjusted to reflect the reverse stock split.

Initial Public Offering

On April 5, 2024, the Company closed its initial public offering ("IPO"), pursuant to which it issued and sold an aggregate of 6,875,000 shares of its common stock at a public offering price of $16.00 per share and on April 19, 2024, the Company issued and sold 548,682 additional shares of its common stock to the underwriters of the IPO pursuant to the partial exercise of their option to purchase additional shares, resulting in net proceeds of approximately $108.0 million, after deducting underwriting discounts, commissions and other offering expenses. Upon the closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into Class A common stock or Class B common stock, as applicable. Converted redeemable convertible preferred stock outstanding as of the date of IPO consisted of 15,906,236 shares that were outstanding as of March 31, 2024 (see Note 6). Following the closing of the IPO, no shares of redeemable convertible preferred stock were authorized or outstanding.

In connection with the closing of its IPO, on April 9, 2024, the Company's certificate of incorporation was amended and restated to authorize 220,000,000 shares of common stock of which 200,000,000 are designated as Class A common stock and 20,000,000 of which are designated as Class B common stock; (ii) eliminate all references to the previously existing series of preferred stock; (iii) authorize 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company's board of directors in one or more series.

The unaudited condensed financial statements as of March 31, 2024, including share and per share amounts, do not give effect to the IPO and related actions as it closed subsequent to March 31, 2024.

Liquidity and Capital Resources

Since its inception, the Company has devoted substantially all its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital to support and expand such activities and providing general and administrative support for these operations. The Company incurred a net loss of $8.4 million for the three months ended March 31, 2024. The Company had an accumulated deficit of $83.6 million as of March 31, 2024. From its inception through March 31, 2024, the Company has financed its operations primarily through issuance of convertible promissory notes, convertible preferred stock financings, a term loan and a license agreement (the "J&J License Agreement") the Company entered in February 2023 with Johnson & Johnson Innovative Medicine (formerly Janssen Pharmaceutica NV), an affiliate of J&J.

As of March 31, 2024, the Company had cash, cash equivalents and marketable securities of $117.9 million, which does not include net proceeds from the IPO. Management believes its existing cash, cash equivalents and marketable securities and net proceeds received from its IPO will be sufficient to support operations for at least 12 months from the issuance of these unaudited condensed financial statements.

As the Company continues to pursue its business plan, it expects to finance its operations through both public and private sales of equity, debt financings or other commercial arrangements, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties. However, there can be no assurance that any additional financing or strategic transactions will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it may need to delay, reduce or eliminate its product development or future commercialization efforts, which could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows. Further, if the Company raises funds through licensing or other similar arrangements with third parties, it may be required to relinquish valuable rights to its technology, future revenue streams, research programs or drug candidates or may be required to grant licenses on terms that may not be favorable to it and/or may reduce the value of its common stock

Unaudited Interim Condensed Financial Statements

The condensed balance sheet as of March 31, 2024, condensed statements of operations and comprehensive loss, condensed statements of convertible preferred stock and stockholders' deficit and cash flows for the three months ended March 31, 2024 and 2023 and related notes to condensed financial statements are unaudited. These unaudited interim condensed financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for the fair statement of the Company's financial position, results of operations and cash flows for the periods presented. The condensed results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the full year or for any other future annual or interim period. The condensed balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date. These interim condensed financial statements should be read in conjunction with the Company's audited financial statements.

2. Summary of Significant Accounting Policies

During the three-month period ended March 31, 2024, there were no changes to our significant accounting policies as described in our registration statement on Form S-1, as amended (File No. 333-278003) as filed with the Securities and Exchange Commission (SEC) pursuant to Rule 424(b) of the Securities Act of 1933, as amended, on April 1, 2024 and declared effective by the SEC on April 4, 2024.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, "Improvements to Income Tax Disclosures." ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024 and for private businesses for annual periods beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statements.

3. Marketable Securities

The Company invests its excess cash in marketable securities, including debt securities, commercial paper, asset-backed securities, yankee debt and U.S. government agency securities.

The following table summarizes the amortized cost and fair value of the Company's marketable securities by major investment category (in thousands).

	As of March 31, 2024			
		Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
US Government agency securities	$ 14,434	$ —	$ (45)	$ 14,389
Certificate of deposit	9,463	6	(1)	9,468
Corporate debt securities	49,544	17	(25)	49,536
Commercial paper	20,751	4	(11)	20,744
Yankee debt	3,882	1	(4)	3,879
Asset-backed securities	3,627	3	(3)	3,627
	$ 101,701	$ 31	$ (89)	$ 101,643

	As of December 31, 2023			
		Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
US Government agency securities	$ 18,883	$ 11	$ —	$ 18,894
Certificate of deposit	5,232	13	—	5,245
Corporate debt securities	52,310	65	(6)	52,369
Commercial paper	28,108	19	(1)	28,126
Yankee debt	2,445	3	—	2,448
Asset-backed securities	2,576	7	(1)	2,582
	$ 109,554	$ 118	$ (8)	$ 109,664

The Company regularly reviews the securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, current and expected future economic conditions. As of March 31, 2024, the Company did not record an allowance for credit loss related to its investment portfolio.

4. Fair Value Measurements

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

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

Assets and liabilities measured at fair value on a recurring basis are as follows (in thousands):

		Fair Value Measurements Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of March 31, 2024:				
Assets:				
Cash equivalents	$ 14,251	$ 14,251	$ —	$ —
US Government agency securities	14,390	13,587	803	—
Certificates of deposits	9,468	—	9,468	—
Corporate debt securities	49,536	—	49,536	—
Commercial paper	20,743	—	20,743	—
Yankee debt	3,879	—	3,879	—
Asset-backed securities	3,628	—	3,628	—
Total financial assets	$ 115,895	$ 27,838	$ 88,057	$ —
Liabilities:				
Preferred stock warrant liability	(227)	—	—	(227)
Total financial liabilities	$ (227)	$ —	$ —	$ (227)
As of December 31, 2023:				
Cash equivalents	$ 14,646	$ 14,646	$ —	$ —
US Government agency securities	18,894	16,360	2,534	—
Certificates of deposits	5,245	—	5,245	—
Corporate debt securities	52,369	—	52,369	—
Commercial paper	28,126	—	28,126	—
Yankee debt	2,448	—	2,448	—
Asset-backed securities	2,582	—	2,582	—
Total financial assets	$ 124,310	$ 31,006	$ 93,304	$ —
Liabilities:				
Preferred stock warrant liability	(109)	—	—	(109)
Total financial liabilities	$ (109)	$ —	$ —	$ (109)

The carrying amounts of the Company's financial instruments, including cash, cash equivalents and marketable securities, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. Included in cash and cash equivalents at March 31, 2024 and December 31, 2023 are money market funds with a carrying value and fair value of $11.9 million and $11.8 million, respectively, based upon a Level 1 fair value assessment.

Preferred Stock Warrant Liability

The preferred stock warrant liability (included on the balance sheet under other long-term liabilities) consists of the fair value of a warrant to purchase Series B convertible preferred stock (see Note 6) and was based on significant unobservable inputs, which represent a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrant utilized the Black-Scholes option-pricing model. Upon the closing of the IPO, the warrant to purchase shares of Series B preferred stock became a warrant to purchase shares of Class A common stock.

The quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the preferred stock warrant liability include the fair value per share of the underlying Series B convertible preferred stock, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model impacting the fair value of the preferred stock warrant is the fair value of the Company's Series B convertible preferred stock as of each remeasurement date. The Company determines the fair value per share of the underlying preferred stock by taking into consideration its most recent sales of its convertible preferred stock as well as additional factors that the Company deems relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant.

The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. The Company has estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends.

The Company classifies this warrant as a liability on its balance sheets that it remeasures to fair value at each reporting date, and the Company recognizes changes in the fair value of the warrant liability as a component of other income (expense) in its statements of operations and comprehensive loss. The Company will continue to recognize changes in the fair value of the warrant liability until the warrant is exercised, expires or qualifies for equity classification.

Significant increases or decreases in any of these inputs in isolation would result in a significantly different fair value measurement. An increase in the risk-free interest rate, and/or an increase in the remaining contractual term or expected volatility, and/or an increase in the fair value of the convertible preferred stock would result in an increase in the fair value of the warrant.

Roll-Forward of Level 3 Financial Instruments

A reconciliation of the Level 3 financial instruments from December 31, 2023 to March 31, 2024 is as follows (in thousands):

	Preferred Stock Warrant Liability
Balance at December 31, 2023	$ 110
Change in fair value of preferred stock warrant liability	117
Balance at March 31, 2024	$ 227

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Accrued compensation expenses	$ 959	$ 1,904
Accrued research and development expenses	1,885	1,546
Accrued professional and consulting expenses	2,316	834
Other accrued expenses	30	101
Total accrued expenses	$ 5,190	$ 4,385

6. Convertible Preferred Stock and Stockholders' Deficit

Under its Amended and Restated Certificate of Incorporation dated April 10, 2023, the Company had a total of 56,571,107 shares of capital stock authorized for issuance, consisting of 39,630,511 shares of common stock, par value of $0.001 per share, and 16,940,594 shares of convertible preferred stock, par value of $0.001 per share. Shares of authorized convertible preferred stock are designated as 1,768,607 shares of Series A convertible preferred stock, 1,429,286 shares of Series A-1 convertible preferred stock, 3,362,377 shares of Series B convertible preferred stock and 10,362,324 shares of Series C convertible preferred stock.

Convertible Preferred Stock

As of March 31, 2024 and December 31, 2023, the Company's Series A, Series A-1, Series B, and Series C convertible preferred stock have been classified as temporary equity in the accompanying balance sheets given that a majority of the Company's board of director seats are held and/or voted upon by convertible preferred stockholders and they could cause certain events to occur requiring redemption of the preferred stock that are outside of the Company's control. The Company has not adjusted the carrying values of the convertible preferred stock to the respective liquidation preferences of such shares as the instruments are currently not redeemable and the Company believes it is not probable that the instruments will become redeemable at this point in time. Adjustments to increase the carrying values to the respective liquidation preferences will be made if and when it becomes probable that an event would occur obligating the Company to pay such amounts.

The authorized, issued, and outstanding shares of convertible preferred stock as of March 31, 2024 consist of the following:

	Shares Authorized	Shares Issued and Outstanding	Liquidation Preference (in thousands)
Series A	1,786,607	1,786,604	$ 10,000
Series A-1	1,429,286	1,423,119	11,179
Series B	3,362,377	3,346,607	32,034
Series C	10,362,324	9,349,906	140,249
	16,940,594	15,906,236	$ 193,462

Series C Convertible Preferred Stock

The Company's convertible preferred stock as of March 31, 2024 has the following characteristics:

1) Dividends

Holders of the Series A and A-1 convertible preferred stock, in preference to any distributions to the holders of common stock, shall be entitled to receive non-cumulative cash dividends at an annual rate of $0.45 and $0.62 per share, respectively. Holders of the Series B convertible preferred stock, in preference to any distributions to the holders of common stock, Series A, and Series A-1 stock, shall be entitled to receive non-cumulative cash dividends at an annual rate of $0.78 per share. Holders of the Series C convertible preferred stock, in preference to any distributions to the holder of common stock, Series A, Series A-1 and Series B convertible preferred stock shall be entitled to receive non-cumulative cash dividends at an annual rate of $1.18 per share. Such dividends are payable only when and if declared by the Company's board of directors.

No such dividends have been declared or paid through March 31, 2024.

2) Preference on Liquidation

The holders of the Series A, Series A-1, Series B, and Series C convertible preferred stock are entitled to receive liquidation preferences upon the liquidation, dissolution or winding-up of the Company at the greater of 1) the Series A, Series A-1, Series B, and Series C convertible preferred stock original issue prices of $5.60, $7.86, $9.52, $15.00 per share, respectively, plus all accrued and declared but unpaid dividends or 2) the amount that would have been payable had all shares been converted to common stock immediately prior to such liquidation, dissolution or winding up of the Company. Liquidation payments to the holders of the Series A and Series A-1 convertible preferred stock have priority and are made in preference to any payments to the holders of common stock. Liquidation payments to the holders of the Series B convertible preferred stock have priority and are made in preference to any payments to the holders of common stock, Series A and Series A-1 convertible preferred stock. Liquidation payments to the holders of the Series C convertible preferred stock have priority and are made in preference to any payments to the holders of common stock, Series A, Series A-1, and Series B convertible preferred stock.

After full payment of the liquidation preference to the holders of the Series A, Series A-1, Series B and Series C convertible preferred stock upon the liquidation, dissolution or winding-up of the Company, the remaining assets, if any, will be distributed ratably to all holders of common stock.

3) Conversion Rights

Each share of outstanding Series A, Series A-1, Series B, and Series C convertible preferred stock is convertible into one share of common stock at the option of the holder, subject to certain anti-dilution adjustments. The conversion rate for the convertible preferred stock is determined by dividing the applicable original issue price, as adjusted for stock splits, by the applicable conversion price. The conversion price is initially the original issue price for such series of convertible preferred stock, but is subject to adjustment for dividends, stock splits, and other distributions. The conversion rate at March 31, 2024 for the Series A, Series A-1, Series B, and Series C convertible preferred stock was 1:1.

Each share of Series A, Series A-1, Series B, and Series C convertible preferred stock will be automatically converted into common stock at the then effective conversion rate (i) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock for the account of the Company in which the gross cash proceeds to the Company are at least $50.0 million or (ii) upon written request for such conversion from the Requisite Investors (defined under the terms of the convertible preferred stock as at least 60% of the holders of preferred stock).

4) Redemption Rights

The holders of Series A, Series A-1, Series B and Series C convertible preferred stock do not have any redemption rights.

5) Voting

The holder of each share of Series A, Series A-1, Series B and Series C convertible preferred stock generally vote together with the shares of common stock as a single class, but also have class vote approval rights as provided by the Company's certificate of incorporation or as required by applicable law.

Common Stock

As of March 31, 2024, of the authorized 39,630,511 shares of common stock, 2,384,446 shares of Class A common stock are issued and outstanding. No shares of Class B common stock are outstanding. The Company has two classes of common stock: the Class A common stock and Class B common stock. Class A common stock has one vote per share and Class B common stock has no votes per share.

Voting, dividend, and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights, preferences and privileges of the holders of the convertible preferred stock. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders.

Common stock reserved for future issuance consisted of the following:

	As of March 31, 2024
Convertible preferred stock	15,906,236
Common stock options granted and outstanding	2,881,867
Shares available for issuance under the 2012 Incentive Plan	260,209
Preferred stock warrant	15,764
Total common stock reserved for future issuance	19,064,076

Stock Options

In 2012, the Company adopted the 2012 Equity Incentive Plan (the "Plan"), which allowed for the issuance of incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock, restricted stock units, and other stock awards (collectively "Stock Awards"). The Plan was established to secure and retain the services of the group of persons eligible to receive Stock Awards and to provide additional incentives to its employees, directors, and consultants of the Company. Under the Plan, the Company can offer ISOs to employees and NSOs to employees, non-employee directors, and consultants. The Plan allows the Company to issue stock awards for shares of its common stock up to a total of 3,429,327 shares, subject to appropriate adjustments for stock splits, combinations and other similar events for issuance pursuant to awards made under the Plan.

Under the Plan, the exercise price of each ISO shall be established in the sole discretion of the Company's board of directors (or any of the committees of the Company's board of directors); provided, however, that (i) the exercise price per share for an ISO shall not be less than the fair market value for shares of the Company's common stock on the date of grant and (ii) the exercise price per share of an ISO granted to an optionee who on the date of the grant owns stock possessing more than 10% stockholder of the Company shall not be less than 110% of the fair market value of a share of its common stock on the date of grant and the option shall not be exercisable after five years from the date of grant.

The options that are granted under the Plan are exercisable at various dates as determined upon grant and terminate within ten years of the date of grant, unless the optionee owns 10% or more of the common shares at which point the expiration period is 5 years, or upon the employee's termination (whereupon the terminated employee has ninety days after termination to exercise vested options from the date of termination). The vesting period generally occurs over four years.

Stock option activity under the Plan is as follows:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2023	2,674,457	$ 5.93	7.22	$ 13,453
Options granted	242,282	16.18	—	—
Options exercised	(34,876)	3.53	—	—
Options cancelled and forfeited	—	—	—	—
Options expired	—	—	—	—
As of March 31, 2024	2,881,863	$ 6.80	7.18	$ 27,022
Options vested and expected to vest as of March 31, 2024	2,881,863	$ 6.80	7.18	$ 27,022
Options exercisable as of March 31, 2024	2,019,302	$ 4.46	6.15	$ 23,656

The aggregate intrinsic value of options exercised during the period ended March 31, 2024 was $0.3 million, determined as of the date of exercise. Options exercisable includes options which are not vested, but are available to be early exercised as of March 31, 2024.

The Company estimated the fair value of stock options using the Black-Scholes valuation model. The Company accounts for any forfeitures of options when they occur. Previously recognized compensation expense for an award is reversed in the period that the award is forfeited. The fair value of stock options was estimated using the following weighted-average assumptions:

	Three Months Ended March 31,	
	2024	2023
Assumptions:		
Expected term (in years)	5.94	6.08
Expected volatility	111%	90%
Risk free interest rate	4.18%	3.40%
Dividend yield	—	—

The weighted-average grant-date fair value per share of stock options granted during the period ended March 31, 2024 was $13.66 per share, respectively. The Company recorded $0.4 million and $0.4 million in stock-based compensation expense in general and administrative and research and development, respectively, for the period ended March 31, 2024. The Company recorded $0.3 million and $0.2 million in stock-based compensation expense in general and administrative and research and development, respectively, for the period ended March 31, 2023.

As of March 31, 2024 there was approximately $9.2 million of total unrecognized stock-based compensation expense related to awards granted under the Plan, which is expected to be recognized over a weighted-average period of approximately 1.3 years.

7. License Agreement

In February 2023, the Company entered into the J&J License Agreement, pursuant to which the Company granted J&J an exclusive, worldwide license to develop, manufacture and commercialize PIPE-307 in all indications. The agreement allows the Company to elect, at its sole discretion and cost, to conduct a Phase 2 trial of PIPE-307 for patients with multiple sclerosis. After such trial, J&J may, at its sole discretion, further develop PIPE-307 for patients with multiple sclerosis. Additionally, upon J&J deciding to conduct a first Phase 3 clinical trial for a product using PIPE-307, the agreement allows the Company the option to co-fund a portion of all Phase 3 and subsequent development costs for PIPE-307, with such cost capped annually. If the Company opts to fund such development costs, then the royalties the Company is eligible to receive will increase. Pursuant to the terms of the agreement, the Company received an upfront, non-refundable and non-creditable payment of $50.0 million upon transferring the license and know-how, existing inventory and manufacturing technology. The Company is also eligible to receive approximately $1.0 billion in non-refundable, non-creditable milestone payments. Additionally, the Company is eligible to receive tiered royalties in the low-double digit to high-teen percent range on net sales of products containing PIPE-307.

The Company sold approximately 1.7 million shares of series C convertible preferred stock to JJDC, an affiliate of J&J, at $15.00 per share, for an aggregate purchase price of approximately $25.0 million, in April 2023. The Company determined that this preferred stock purchase was at fair value as other new investors purchased shares of preferred stock at the same price.

The Company concluded that J&J represented a customer and applied relevant guidance from ASC 606 to evaluate the appropriate accounting for the J&J License Agreement. The Company evaluated the J&J agreement and concluded that it had promises to transfer a license of functional intellectual property, know-how, existing inventory and manufacturing technology (each of which was determined to be a distinct performance obligation). Control of the promised goods was transferred to J&J in the second quarter of 2023, and the $50 million upfront payment was recognized in May 2023 upon satisfaction of the performance obligations. The remaining consideration consists of future contingent milestone-based payments and sales-based royalties. As of March 31, 2024, all variable consideration under the J&J License Agreement was fully constrained.

In August 2023, the Company elected to conduct a Phase 2 trial using PIPE-307 for patients with multiple sclerosis, which was considered a contract modification under the accounting guidance that added promised goods or services that are distinct at a price that is below the standalone selling price. Therefore, the Company accounted for the modification as a termination of the existing contract and creation of a new contract. Accordingly, the amount of consideration to be allocated to the remaining performance obligations consists of future contingent milestone-based payments and sales-based royalties, all of which were constrained. The only remaining performance obligation is the promise to conduct the Phase 2 trial as the other performance obligations had been satisfied prior to the modification date. Accordingly, the variable consideration allocated to the Phase 2 trial will be recognized as the study is completed using a cost-based measure of progress and when the amounts are no longer probable of a significant reversal. As of March 31, 2024, no amounts had been recognized related to the Phase 2 trial.

8. Net Loss Per Share

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

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss	$ (8,417)	$ (4,824)
Denominator:		
Weighted average common shares issued	2,369,067	2,288,358
Less: weighted average unvested common stock issued upon early exercise of stock options	—	10,803
Weighted average shares used to compute net loss per common share, basic and diluted	2,369,067	2,277,555
Net loss per share, basic and diluted	$ (3.55)	$ (2.12)

The Company's potentially dilutive securities, which include convertible preferred stock, preferred stock warrants, common stock issued upon early exercise of stock options, common stock subject to repurchase, common stock options, and the investor rights and obligations liability, have been excluded from the computation of diluted net loss per share for the three months ended March 31, 2024 and 2023 as the effect would reduce the net loss per share. Therefore, the weighted-average number of shares common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common securities, presented based on amounts outstanding at each period end, from the computation of diluted net income (loss) per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	March 31, 2024	March 31, 2023
Convertible preferred stock (as converted to common stock)	15,906,273	11,889,698
Common stock options	2,881,863	2,201,451
Unvested common stock issued upon early exercise of stock options	—	17,130
Preferred stock warrant (as converted to common stock)	15,764	15,764
	18,803,900	14,124,043

9. Subsequent Events

The Company's board of directors approved a one-for-5.5972 reverse stock split of its issued and outstanding common and preferred stock, effective on April 1, 2024. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the effects of the reverse stock split. Shares of common stock underlying outstanding stock options and preferred stock warrants were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

On April 4, 2024, the Company's registration statement on Form S-1 (File No. 333-278003) relating to its initial public offering ("IPO") of its common stock was declared effective by the SEC and the shares of its common stock began trading on the Nasdaq Global Select Market (Nasdaq) on April 4, 2024. The public offering price of the shares sold in the IPO was $16.00 per share. The IPO closed on April 9, 2024, pursuant to which the Company sold 6,875,000 shares of common stock, for gross proceeds of approximately $110.0 million. On April 19, 2024, the underwriters elected to partially exercise the over-allotment option purchasing 548,682 shares for gross proceeds of an additional $8.2 million.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited condensed financial statements and notes thereto as of and for the year ended December 31, 2023 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are included in our final prospectus filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b) under the Securities Act of 1933, as amended ("Securities Act") on April 8, 2024 ("Prospectus") that forms a part of our Registration Statement on Form S-1 (File No. 333-278003).

This Quarterly Report on Form 10-Q may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such forward-looking statements, which represent our intent, belief, or current expectations, involve risks and uncertainties. We use words such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements may include, but are not limited to, statements concerning projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a clinical stage biopharmaceutical company focused on discovering and developing novel, oral small molecule therapies that target biological pathways associated with specific clinical impairments for the treatment of neuroscience, inflammation and immunology ("NI&I") indications with high unmet need.

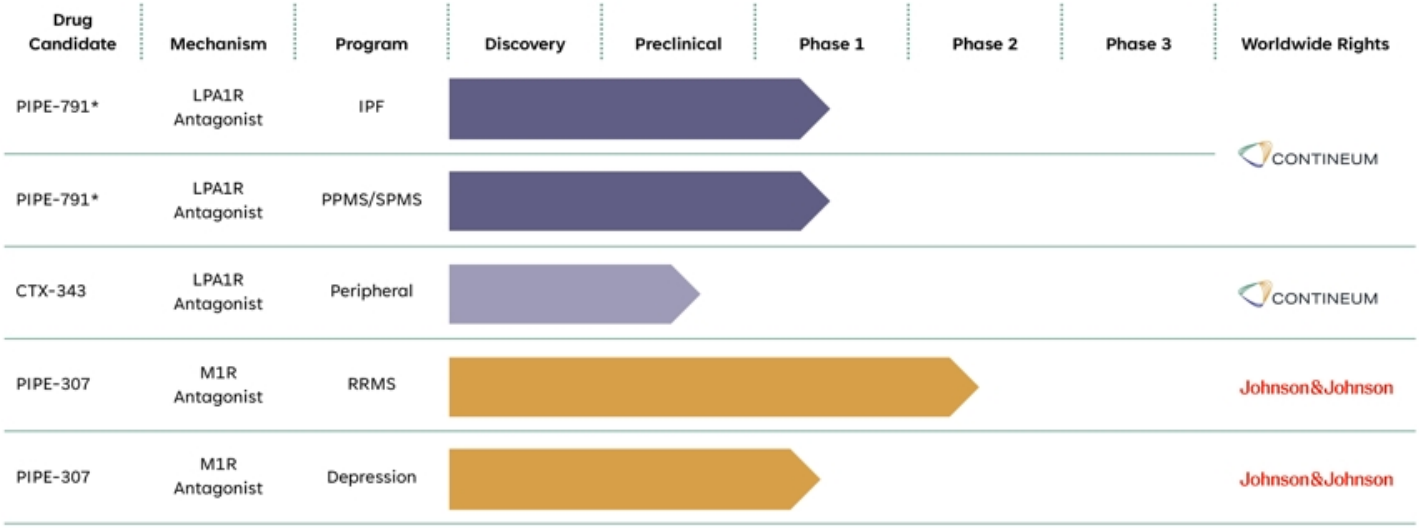
We have focused our efforts on developing selective compounds targeting challenging molecular pathways, and through these efforts, have built a portfolio of small molecule drug candidates.

Our wholly-owned lead asset, PIPE-791, is a novel, brain penetrant, small molecule inhibitor of lysophosphatidic acid 1 receptor ("LPA1R") in development for idiopathic pulmonary fibrosis ("IPF") and Progressive multiple sclerosis ("Progressive MS"). LPA1R antagonism is a clinically validated mechanism, and we believe that our preclinical studies and Phase 1 healthy volunteer data support the continued development of PIPE-791 for both IPF and Progressive MS. Specifically, based on its high bioavailability, low plasma protein binding, and long receptor residence time in our preclinical studies compared to the preclinical data of other LPA1R antagonists that we know are currently in development, we also believe PIPE-791 has the potential to be a differentiated LPA1R therapy. We completed a Phase 1 clinical trial of PIPE-791 in healthy volunteers in support of clinical development in both IPF and Progressive MS. We plan to submit a clinical trial application ("CTA") to the Medicines and Healthcare products Regulatory Agency ("MHRA") to commence a Phase 1b open-label trial of PIPE-791 to measure the relationship of pharmacokinetics ("PK") to lung and brain receptor occupancy by positron emission tomography ("PET") imaging in 2024. This Phase 1b trial will inform dose selection for our planned future Phase 2 trials of PIPE-791 in IPF and Progressive MS.

Our second drug candidate, PIPE-307, is a novel, small molecule selective inhibitor of the muscarinic type 1 M1 receptor ("M1R"), in development for depression and relapse-remitting multiple sclerosis ("RRMS"). M1R antagonism has been clinically validated in third-party trials in both depression and RRMS by scopolamine and clemastine, respectively. We have completed two Phase 1 trials of PIPE-307 in healthy volunteers and have initiated a Phase 2 trial of PIPE-307 for the potential treatment of RRMS. To our knowledge, PIPE-307 is the most clinically advanced selective M1R antagonist in development. We are developing PIPE-307 in collaboration with Johnson & Johnson.

In addition, we are leveraging our drug discovery capabilities synergistically with our clinical portfolio. In January 2024, we nominated and commenced preclinical studies for CTX-343, a peripherally-restricted (unable to cross the blood brain barrier) LPA1R antagonist. In parallel, we are actively conducting preclinical and discovery-phase experiments targeting other NI&I indications where our internally-discovered molecules may have therapeutic potential.

We are currently focused on developing the following product candidates in our pipeline:



* Single Phase 1b PET clinical trial of PIPE-791 for the potential treatment of IPF and Progressive MS.

We expect our operating expenses to significantly increase as we continue to develop, conduct clinical trials, and seek regulatory approvals for our drug candidates, engage in other research and development activities to expand our pipeline of drug candidates, expand our operations and headcount, maintain and expand our intellectual property portfolio, and, if we obtain approval for one or more of our drug candidates, launch commercial activities. We also expect to incur additional operating expenses as we begin operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing and scope of our clinical trials and our expenditures on other research and development activities.

As we continue to pursue our business plan, we expect to finance our operations through both public and private sales of equity, debt financings or other commercial arrangements, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties. However, there can be no assurance that any additional financing or strategic transactions will be available to us on acceptable terms, if at all. If events or circumstances occur such that we do not obtain additional funding, we may need to delay, reduce or eliminate our product development or future commercialization efforts, which could have a material adverse effect on our business, results of operations or financial condition. Further, if we raise funds through licensing or other commercial arrangements with third parties, we may be required to relinquish valuable rights to our technology, future revenue streams, research programs or drug candidates or may be required to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock.

Collaboration

In February 2023, we entered into the J&J License Agreement with J&J, pursuant to which we granted J&J an exclusive, worldwide license to develop, manufacture and commercialize PIPE-307 in all indications.

J&J is generally responsible for all development, manufacturing and commercialization activities for PIPE-307. Upon J&J conducting a first Phase 3 clinical trial for a product using PIPE-307, we have an opt-in right to fund a portion of all Phase 3 and subsequent development costs for PIPE-307. If we opt to fund such development costs, then the royalties we are eligible to receive will increase by one to two percentage points.

We are conducting, at our own expense, a Phase 2 clinical trial of PIPE-307 in patients with RRMS. J&J has the right to discontinue our clinical trial if it has good faith concerns that this trial presents safety risks or could have a material adverse effect on its development or commercialization of PIPE-307. In addition, J&J has the right, in its sole discretion, to further develop or to elect not to develop PIPE-307 for this indication.

The J&J License Agreement expires on a licensed product-by-product and country-by-country basis upon the last to occur of: (i) the expiration of the last-to-expire licensed patent claim covering the composition of matter of the licensed compound in such licensed product in such country; (ii) the expiration of exclusive marketing rights conferred by a regulatory authority or applicable law (other than patent exclusivity) for such licensed product in such country; and (iii) ten years after the first commercial sale of such licensed product in such country. Either party may terminate the J&J License Agreement in the event of an uncured material breach by the other party or a bankruptcy or insolvency of the other party. J&J may terminate the J&J License Agreement without cause upon prior written notice to us. Upon any termination, all license rights granted to J&J terminate.

Financial Operations Overview

Revenue

We recognize license revenues as identified performance obligations are satisfied or other events occur, specifically related to our J&J License Agreement. Pursuant to the terms of the J&J License Agreement, we received an upfront payment of $50.0 million in May 2023. We are also eligible to receive approximately $1.0 billion in non-refundable, non-creditable milestone payments, pursuant to the terms of the J&J License Agreement. Additionally, we are eligible to receive tiered royalties in the low-double digit to high-teen percent range on net sales of products containing PIPE-307.

Operating Expenses

Research and Development

Research and development costs consist primarily of costs incurred for the unallocated internal research and development costs:

Direct costs include:

- employee-related expenses, including salaries, related benefits, travel that can be directly attributable to each research project;
- expenses incurred in connection with research, laboratory consumables and preclinical studies;
- expenses incurred in connection with conducting clinical trials, including investigator grants and site payments for time and pass-through expenses and expenses incurred under agreements with clinical research organizations ("CROs"), other vendors or central laboratories and service providers engaged to conduct our trials;
- the cost of consultants engaged in research and development related services;
- the cost to manufacture drug products for use in our preclinical studies and clinical trials; and
- costs related to regulatory compliance.

Unallocated internal research and development costs include:

- employee-related expenses, including salaries, related benefits, travel that cannot be directly attributable to a specific research project;
- stock-based compensation expenses for employees engaged in research and development functions; and
- facilities, depreciation and other related expenses.

We expense our research and development costs as they are incurred. We record advance payments for goods or services to be received in the future for use in research and development as prepaid expenses. We then expense the prepaid amounts as the related goods are delivered or the services are performed.

We track outsourced development costs, consultant costs and other external research and development costs such as third-party contract costs relating to manufacturing, clinical trial activities, translational medicine and toxicology activities to specific programs. We allocate employee related costs including salaries and related benefits based upon the level of effort for each specific project. Certain employee activities that cannot be allocated to any one specific project or management related activities are considered indirect costs. The following tables summarize our research and development expenses for the periods ended March 31, 2024 and 2023. The direct external development program expenses reflect external costs attributable to our clinical development and preclinical programs and personnel costs that can be directly attributed to a development program. The unallocated internal research and development costs include unallocated personnel costs, facility costs, stock-based compensation, laboratory consumables and discovery and research related activities.

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Direct external development program expense		
PIPE-791	$ 2,861	$ 1,106
PIPE-307	2,075	614
CTX-343	312	77
Others	1,104	838
Unallocated internal research and development costs		
Personnel related	369	290
Stock-based compensation	388	236
Facilities costs	219	209
Other	450	262
Total research and development costs	$ 7,778	$ 3,632

Research and development activities are central to our business model. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future clinical trial design and various regulatory requirements, many of which we cannot determine with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our drug candidates and our costs may increase if we exercise our opt-in right to fund a portion of all Phase 3 and subsequent development costs for PIPE-307 pursuant to the J&J License Agreement. However, we expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and for the foreseeable future.

The successful development of our drug candidates is highly uncertain. This is due to numerous risks and uncertainties, including the following:

- successful completion of preclinical studies and clinical trials;
- delays in regulators or institutional review boards ("IRBs") authorizing us or our investigators to commence or continue our clinical trials;
- our ability to negotiate agreements with clinical trial sites or CROs;
- the number of clinical sites included in our clinical trials;
- raising additional funds necessary to complete clinical development of our drug candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- establishing and qualifying manufacturing capabilities for clinical supplies of our drug candidates, whether directly or through qualified third party manufacturers;
- our ability to receive necessary regulatory approvals from the U.S. Food and Drug Administration (:FDA") and comparable governmental bodies outside the United States;
- our decision to elect to fund a portion of Phase 3 and subsequent development costs for PIPE-307;
- coverage for our products by governmental and third party payors;
- protecting and enforcing our rights in our intellectual property portfolio;
- our ability to successfully compete with our competitors and their product offerings; and
- maintaining a continued acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of our drug candidates may significantly impact the costs and timing associated with the development of our drug candidates. We may never succeed in obtaining regulatory approval for any of our drug candidates or successfully commercialize our products, even if approved.

General and Administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include legal fees relating to intellectual property, patent applications, and corporate matters, professional fees for accounting and consulting services and facility-related costs.

We expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development activities, the growth of our business operations and headcount and to reflect increased operating expenses as we begin operating as a public company. These increased costs will likely include increased expenses related to audit, legal, regulatory services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other Income (Expense)

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists of (i) interest on our outstanding Loan Agreement with First Citizens, and (ii) amortization of our debt discount associated with our loan and security agreement recorded in connection with the fair value of the warrant issued to First Citizens, the debt issuance costs incurred and the obligation to make a final payment fee. We repaid all of the outstanding principal on the First Citizens loan as of June 2023.

Results of Operations

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

The following table summarizes our results of operations (in thousands) for the periods indicated:

	Three Months Ended March 31,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 7,778	$ 3,632	$ 4,146
General and administrative	2,152	1,483	669
Total operating expenses	9,930	5,115	4,815
Loss from operations	(9,930)	(5,115)	(4,815)
Other income (expense)			
Interest income	1,636	401	1,235
Interest expense	—	(92)	92
Change in fair value of preferred stock warrant liability	(117)	—	(117)
Other expense	(6)	(18)	12
Total other income	1,513	291	1,222
Net loss	$ (8,417)	$ (4,824)	$ (3,593)

Research and development expenses. Research and development expenses were $7.8 million and $3.6 million for the three months ended March 31, 2024 and 2023, respectively. The increase of $4.2 million was primarily due to a $2.0 million increase in contract research organization costs primarily related to our on-going Phase 2 clinical trial for PIPE-307 for the potential treatment of RRMS and our completed Phase 1 healthy volunteer clinical trial for PIPE-791, a $0.9 million increase in expenses for toxicology studies primarily for PIPE-791 and a $0.6 million increase in personnel-related expenses.

General and administrative expenses. General and administrative expenses were $2.2 million and $1.5 million for three months ended March 31, 2024 and 2023, respectively. The increase of $0.7 million was primarily due to a $0.5 million increase in consulting expenses primarily related to an audit completed in accordance with public company audit requirements and $0.1 million increase in personnel-related expenses.

Interest income. Interest income was $1.6 million and $0.4 million for the three months ended March 31, 2024 and 2023, respectively. The increase was due to an increase in funds invested in marketable securities starting in the second quarter of 2023 consisting of net proceeds of $60.1 million from the extension of our Series C convertible preferred stock financing and the receipt of $50.0 million upfront payment pursuant to the J&J License Agreement. We also had an increase in the yields earned on our marketable securities from the three months ended March 31, 2023 to the three months ended March 31, 2024.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses and negative cash flows from operations in nearly every reporting period since our inception and anticipate that we will continue to incur net losses for the foreseeable future. We expect to incur substantial expenditures as we advance our drug candidates through clinical development, undergo the regulatory approval process, engage in other research and development activities to expand our pipeline of drug candidates, expand our operations and headcount, maintain and expand our intellectual property portfolio and, if we obtain approval for one or more of our drug candidates, launch commercial activities. Specifically, in the near term we expect to incur substantial expenses relating to completing our clinical trials and our other product development activities.

Through March 31, 2024, we have funded our operations primarily through the issuance of convertible promissory notes, the private placements of our convertible preferred stock, the J&J License Agreement, and our term loan facility with First Citizens. Through March 31, 2024, we have raised gross proceeds of approximately $194.0 million from the issuance of our convertible preferred stock and promissory notes and have received an upfront payment from the J&J License Agreement of $50.0 million. Our cash equivalents are held in money market funds and marketable securities. At March 31, 2024, we had an accumulated deficit of $83.6 million. In April 2024, we raised an additional $108.0 million in net proceeds from the initial public offering of our shares of Class A common stock (“IPO”). We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, director and officer insurance and other expenses that we did not incur as a private company.

As of March 31, 2024, we had cash, cash equivalents and marketable securities of $117.9 million. Management believes our existing cash, cash equivalents and marketable securities and proceeds received from our IPO will be sufficient to support our operations for at least 12 months from the date of this Quarterly Report on Form 10-Q.

As we continue to pursue our business plan, we expect to finance our operations through both public and private sales of equity, debt financings or other commercial arrangements, which could include milestone payments from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties. However, there can be no assurance that any additional financing or strategic transactions will be available to us on acceptable terms, if at all. If events or circumstances occur such that we do not obtain additional funding, we may need to delay, reduce or eliminate our product development or future commercialization efforts, which could have a material adverse effect on our business, results of operations or financial condition. Further, if we raise funds through licensing or other commercial arrangements with third parties, we may be required to relinquish valuable rights to our technology, future revenue streams, research programs or drug candidates or may be required to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock.

Cash Flows

The following table sets forth a summary of our cash flows for the period indicated (in thousands):

	Three Months Ended March 31,	
	2024	**2023**
Net cash used in operating activities	$ (7,975)	$ (5,244)
Net cash provided by investing activities	8,731	9,355
Net cash used in financing activities	(18)	(617)
Net increase in cash and cash equivalents	$ 738	$ 3,494

Operating Activities

Net cash used in operating activities was $8.0 million and $5.2 million for the three months ended March 31, 2024 and 2023, respectively. The net cash used in operating activities for the three months ended March 31, 2024 was primarily due to our net loss of $8.4 million, partially offset by $0.1 million of non-cash charges such as stock-based compensation, depreciation and amortization, amortization of premiums/discounts on marketable securities and amortization of right-of-use assets and a $0.3 million change in operating assets and liabilities.

The net cash used in operating activities for the three months ended March 31, 2023 was primarily due to our net loss of $4.8 million and a $1.0 million change in operating assets and liabilities, partially offset by $0.6 million of non-cash charges such as stock-based compensation, depreciation and amortization, amortization of premiums/discounts on marketable securities, amortization of debt discount, amortization of right-of-use assets.

Investing Activities

Net cash provided by investing activities was $8.7 million for the three months ended March 31, 2024, which primarily consisted of $39.5 million of sales and maturities of marketable securities, partially offset by $30.7 million of purchases of marketable securities and $0.1 million of purchases of property and equipment. Net cash provided by investing activities was $9.4 million for the three months ended March 31, 2023, which primarily consisted of $18.6 million of proceeds from sales and maturities of marketable securities, partially offset by $9.2 million of purchases of marketable securities.

Financing Activities

Net cash used in financing activities was approximately $18,000 for the three months ended March 31, 2024, primarily due to payment of deferred offering costs offset by proceeds from the exercise of stock options. Net cash used in financing activities was $0.6 million for the three months ended March 31, 2023, primarily due to principal payments on the term loan of $0.6 million.

Funding Requirements

We expect our operating expenses to significantly increase as we continue to develop and seek regulatory approvals for our drug candidates, engage in other research and development activities to expand our pipeline of drug candidates, expand our operations and headcount, maintain and expand our intellectual property portfolio, and, if we obtain approval for one or more of our drug candidates, launch commercial activities. Management believes our existing cash, cash equivalents and marketable securities and proceeds received from the IPO will be sufficient to support our operations for at least 12 months from the date of this Quarterly Report on Form 10-Q. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and our actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing our drug candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of, our clinical trials and preclinical studies for our drug candidates or other potential drug candidates or indications which we are pursuing or may choose to pursue in the future;
- the outcome, timing and costs of regulatory review of our drug candidates;
- the costs and timing of manufacturing for our drug candidates;
- our efforts to enhance our operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities expand;
- the costs and timing of establishing or securing manufacturing facilities for our drug candidates;

- the costs and timing of establishing sales and marketing capabilities if any of our drug candidates are approved;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements;
- the financial terms of any such agreements that we may enter into;
- our decision to elect to fund a portion of Phase 3 and subsequent development costs for PIPE-307;
- the costs of obtaining, maintaining and enforcing our patent and other intellectual property rights; and
- costs associated with any drug candidates, products or technologies that we may in-license or acquire.

Until such time as we can generate significant revenue from sales of our drug candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings or other commercial arrangements, including collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties. We may be unable to raise additional funds or enter into such commercial arrangements when needed, on favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may be required to relinquish valuable rights to our drug candidates, future revenue streams or research programs or may be required to grant licenses on terms that may not be favorable to us and may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or through commercial arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our drug candidates even if we would otherwise prefer to develop and market such drug candidates ourselves.

Contractual Obligations and Commitments

Our contractual obligations and commitments relate to our operating leases that relate primarily to our leases of office and laboratory space in San Diego, California. Our total contractual commitments for our lease agreements amount to approximately $7.8 million as of March 31, 2024.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of financial condition and results of operations are based upon our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosures. On an ongoing basis, our actual results may differ significantly from our estimates.

There have been no material changes to our critical accounting estimates from those described under our “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Estimates” included in our Prospectus, except that from the effectiveness date of our registration statement on Form S-1 (File No. 333-278003), our common stock is publicly traded and we therefore no longer require common stock valuations.

Emerging growth company and smaller reporting company status

We are an “emerging growth company”, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. We will remain an emerging growth company until the earlier of (i) December 31, 2029, the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (ii) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.235 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our voting and non-voting common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter .

Recently Issued Accounting Pronouncements

See Note 2 to our financial statements for recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures. Based on this evaluation of our disclosure controls and procedures as of March 31, 2024, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2024, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in various legal proceedings and claims that arise in the ordinary course of our business activities. We are not currently a party to any material legal proceedings. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

Investing in our common stock is speculative and involves a high degree of risk. Before investing in our common stock, you should consider carefully the risks and uncertainties described below, together with the other information contained in this report, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. This report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Special Note Regarding Forward-Looking Statements" elsewhere in this report.

Risks Related to Development, Clinical Testing, and Regulatory Approval

We are heavily dependent on the success of PIPE-791, our lead drug candidate, and PIPE-307, both of which are in the early stages of clinical development. If these drug candidates do not progress through clinical development, eventually receive regulatory approval or, even if approved, are not successfully commercialized, our business will be materially adversely harmed.

We currently have no products that are approved for commercial sale and may never be able to develop a marketable product. To date, we have invested a significant portion of our efforts and financial resources on the development of PIPE-791 and PIPE-307. We wholly-own, and are pursuing the clinical development of, PIPE-791 for the treatment of IPF and Progressive MS. In February 2023, we entered into the J&J License Agreement, pursuant to which we granted J&J an exclusive, worldwide license to develop, manufacture and commercialize PIPE-307 in all indications in exchange for an upfront payment and the right to receive future milestone payments and royalties. We are conducting a Phase 2 clinical trial of PIPE-307 for the potential treatment of RRMS, and J&J has announced its intention to initiate a Phase 2 clinical trial of PIPE-307 in depression in 2024. After we complete the Phase 2 clinical for PIPE-307 for the potential treatment of RRMS, J&J has sole discretion to determine whether to pursue further development of PIPE-307 for this indication. Our future success is, therefore, dependent on our ability to successfully complete clinical development for, obtain regulatory approval for, and successfully commercialize PIPE-791 and on J&J's efforts to successfully complete clinical development for, obtain regulatory approval for, and successfully commercialize PIPE-307, which in each case may never occur. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to PIPE-791, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval, establishing commercial scale manufacturing, and significant sales, marketing, and distribution efforts before we can generate any revenues from any commercial sales. We cannot be certain that we or J&J, respectively, will be able to successfully complete any of these activities or that, even if PIPE-791 and/or PIPE-307 receive regulatory approval, such products will be able to successfully compete against therapies and technologies offered by other companies.

The research, testing, manufacturing, labeling, approval, sale, packaging, marketing, and distribution of drug products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. We are not permitted to market or sell PIPE-791, and J&J will not be permitted to market or sell PIPE-307, in the United States until we or J&J, as applicable, receive approval of a New Drug Application ("NDA") from the FDA for such drug candidate. Further, we are not permitted to market or sell PIPE-791, and J&J will not be permitted to market or sell PIPE-307, in any foreign countries until we or J&J, as applicable, receive the requisite approvals from such countries. Neither we nor J&J have submitted an NDA to the FDA or comparable applications to other regulatory authorities for PIPE-791 or PIPE-307, respectively, in any indication. Neither party will be in a position to do so for several years, if ever. If we are unable to obtain the necessary regulatory approvals for PIPE-791 in any country, we will not be able to commercialize such drug candidate in that country. Similarly, if J&J is unable to obtain the necessary regulatory approvals for PIPE-307 in any country, it will not be able to commercialize such drug candidate in that country. In both cases, our financial position will be materially adversely affected, and we may not be able to generate sufficient revenue to continue our business.

Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes. The results of earlier preclinical studies and clinical trials, including those conducted by third parties, may not be predictive of future results. If clinical trials for the drug candidates we develop do not meet safety or efficacy endpoints or are prolonged or delayed, these drug candidates may not receive the required regulatory approvals, and therefore could not be commercialized on a timely basis or at all. Further, the results of our preclinical studies, clinical trials, or analyses may not be indicative of results that may be obtained in later trials.

Before obtaining marketing approval from regulatory authorities for the sale of the drug candidates we develop, these drug candidates must undergo extensive clinical trials to demonstrate their safety and efficacy in humans. The research and development of drugs is extremely risky. Only a small percentage of drug candidates that enter the development process ever receive marketing approval. Failure or delay can occur at any time during the clinical trial process. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing drug candidates, including conducting preclinical studies and early-stage clinical trials. Clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials for the drug candidates we develop will be conducted as planned or completed on schedule, if at all. Our inability to successfully complete preclinical and clinical development for PIPE-791 could result in additional costs to us and negatively impact our ability to generate revenue. Similarly, if J&J cannot successfully complete preclinical and clinical development for PIPE-307, we will not be eligible to receive future milestone payments or royalties under the J&J License Agreement. As a result, our future success is dependent on our ability and the ability of J&J to successfully develop, obtain regulatory approval for, and then successfully commercialize PIPE-791 and PIPE-307, respectively. We currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product. Further, we may never generate additional milestone payments or royalties under the J&J License Agreement.

PIPE-791 and PIPE-307 are currently in the early stages of clinical development. We completed a Phase 1 clinical trial of PIPE-791 in healthy volunteers in support of clinical development in both IPF and Progressive MS. We plan to submit a CTA to the MHRA to commence a Phase 1b open-label trial of PIPE-791 to measure the relationship of PK to lung and brain receptor occupancy by PET imaging in 2024. This Phase 1b trial will inform dose selection for our planned future Phase 2 trials of PIPE-791 in IPF and Progressive MS. We have completed two Phase 1 trials of PIPE-307 in healthy volunteers and have initiated a Phase 2 trial of PIPE-307 for the potential treatment of RRMS. J&J has announced its intention to initiate a Phase 2 trial for PIPE-307 for the treatment of depression in 2024. The results from our preclinical studies and the early clinical trials for these drug candidates may not be predictive of the results of the current clinical trials being conducted and any later-stage clinical trials conducted for these drug candidates. In addition, results of third-party studies, as well as our evaluations of third-party compounds, may not be predictive of results for our drug candidates. Drug candidates in clinical trials, including PIPE-791 and PIPE-307, may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and early-stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advancing through the clinical trial process due to lack of efficacy or adverse safety profiles, notwithstanding earlier promising results. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect in subsequent clinical trials that have pre-specified end points or may not be considered adequate by regulatory authorities. Even if the current clinical trials for PIPE-791 and PIPE-307 are completed as planned, we cannot be certain that their results will support the safety and efficacy requirements sufficient to pursue later clinical trials and eventually obtain regulatory approval, and, as a result, we may never generate commercial revenues from these drug candidates.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria, relatively smaller sample size in earlier clinical trials, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret the data from these trials as favorably as we do, which may further delay, limit or prevent marketing approval. Furthermore, as more drug candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, PIPE-791 and/or PIPE-307 may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies, or having successfully advanced through early-stage clinical trials. The failure of any of drug candidate to demonstrate safety and efficacy in any clinical trial or for any indication could negatively impact the perception of the use of this drug candidate to treat other indications and the perception of any other drug candidate we develop (and therefore hinder the ability to successfully move forward with the development of the drug candidate in other indications or the development of our other drug candidates) or cause regulatory authorities to require additional testing before approving any of the drug candidates we develop.

Our lead drug candidate, PIPE-791, and our partnered drug candidate, PIPE-307, are each in the early-stages of clinical development for each indication, and as a result, their risk of failure is high. We are unable to predict if PIPE-791 or PIPE-307 will prove safe or effective in humans for any indication or that any of our future drug candidates that advance into clinical trials will prove safe or effective in humans or will obtain marketing approval. If we or J&J are unable to complete current and future planned clinical trials for PIPE-791 and PIPE-307, respectively, due to safety concerns, or if the results of these trials are not satisfactory to convince regulatory authorities of their safety or efficacy, we and/or J&J will not be able to obtain marketing approval for commercialization. Even if we and/or J&J are able to obtain marketing approvals for PIPE-791 and PIPE-307, respectively, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of PIPE-791 or to generate royalties or achieve milestones from PIPE-307. Moreover, if we or J&J are not able to differentiate PIPE-791 and PIPE-307, respectively, against other approved products for the indications being targeted for PIPE-791 and PIPE-307, or if any of the other circumstances described above occur, our business would be materially harmed and our ability to generate revenue from these drug candidates would be severely impaired.

We may experience delays in initiating and completing any clinical trials that we intend to conduct, including our current clinical trials for PIPE-791 and PIPE-307, and we do not know whether our clinical trials will begin on time, need to be redesigned, enroll sufficient numbers of patients on time, or be completed on schedule, or at all. J&J will face similar concerns for any future clinical trials it conducts for PIPE-307. A clinical trial can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of the clinical trial;
- obtaining regulatory approval to commence the clinical trial;
- reaching an agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB approval at each site within the United States or independent ethics committee ("IEC") or other approval at sites outside the United States;
- recruiting suitable patients to participate in the clinical trial in a timely manner and in sufficient numbers;
- having patients complete the clinical trial or return for post-treatment follow-up;
- imposition of a clinical hold by regulatory authorities, including as a result of unforeseen safety issues or side effects or failure of clinical trial sites or investigators to adhere to regulatory requirements or follow trial protocols;
- clinical sites or investigators deviating from the clinical trial protocol or dropping out of the clinical trial, potentially necessitating the addition of new sites or investigators;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or deviating from the clinical trial protocol;
- addressing patient safety concerns that arise during the clinical trial, including a decision by the initiating party, regulatory authorities, or IRBs, IECs or other relevant entities to suspend or terminate the clinical trial;
- adding a sufficient number of clinical trial sites;
- increased or unforeseeable costs in conducting a clinical trial;
- timely manufacturing sufficient quantities of a drug candidate, and accessing sufficient quantities of other materials (e.g. placebo, equipment) for use in the clinical trial; and
- potential disruptions caused by public health emergencies ("PHEs") such as COVID-19, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors.

A clinical trial may also be suspended or terminated by the initiating party, the IRBs or IECs of the institutions in which such clinical trial is being conducted, the FDA or other regulatory authorities, or recommended for termination by a Data and Safety Monitoring Board ("DSMB") for such trial. Such authorities may impose a suspension or termination or recommend an alteration due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, such as Good Clinical Practice ("GCP") requirements, or the clinical trial protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Further, J&J has the right to discontinue the clinical trial we are currently conducting for PIPE-307 if it has good faith concerns that such study presents safety risks or could present material adverse effects for the development or commercialization of PIPE-307 generally.

Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in the section titled "—Risks related to our dependence on third parties."

If the commencement or completion of any clinical trials for PIPE-791 or PIPE-307 is delayed, or if a clinical trial is terminated prior to completion, the commercial prospects of the applicable drug candidate could be harmed, and our ability to generate revenues or royalties from such drug candidate may be delayed. In addition, any delays in our clinical trials could increase our costs, slow the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences could materially harm our business, financial condition and results of operations. In addition, many of the factors that may cause, or lead to, a delay in the commencement or completion of a clinical trial may also ultimately lead to the denial of regulatory approval of the applicable drug candidate.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of a clinical trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of a drug candidate.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are unpredictable, lengthy, and time-consuming, and if we are ultimately unable to obtain regulatory approval for PIPE-791 or any other drug candidates that we develop or J&J is unable to obtain regulatory approval for PIPE-307, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the indication being studied and the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval for an indication may change during a drug candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for PIPE-791, and J&J has not obtained regulatory approval for PIPE-307. It is possible that neither of these drug candidates or future drug candidates will receive the regulatory approvals required for commercialization. We are not permitted to market PIPE-791 or any other drug candidates that we develop in the United States until we receive approval of an NDA from the FDA. Similarly, J&J will not be permitted to market PIPE-307 in the United States until it receives approval of an NDA from the FDA.

Prior to obtaining approval to commercialize a drug candidate in the United States or abroad, the initiating party must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authority, that such drug candidate is safe and effective for its intended indication. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret this data as favorably as the initiating party, which may further delay, limit, or prevent development efforts, clinical trials, or marketing approval. For example, even if we believe the preclinical or clinical data for PIPE-791 in an indication is promising, such data may not be sufficient to support approval by the FDA and other comparable regulatory authorities for this indication. Furthermore, as more competing drug candidates within a class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

The FDA or any foreign regulatory authority can delay, limit, or deny approval of PIPE-791, PIPE-307 or any other drug candidates that we develop for any indication, or require us or J&J, as applicable, to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of a clinical trial;
- the initiating party may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in a clinical trial or by individuals using drugs similar to the drug candidate being studied in the clinical trial, or other products containing an active ingredient in such drug candidate;
- negative or ambiguous results from a clinical trial or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the inability to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with the interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and the initiating party may be required to conduct additional clinical trials;
- the FDA's or the applicable foreign regulatory authority's disagreement regarding the formulation, the labeling, and/or the specifications of a drug candidate;
- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers that produced the drug candidate for use in the clinical trials; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering the clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in the failure of PIPE-791 and/or PIPE-307 to obtain the required regulatory approvals for commercialization in any indication, which would significantly harm our business, results of operations and prospects.

In addition, the FDA or the applicable foreign regulatory authority also may approve a drug candidate for a more limited indication or patient population than originally requested, and the FDA or applicable foreign regulatory authority may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing circumstances could materially harm the commercial prospects for the drug candidates we develop and our business.

We may not be successful in our efforts to identify and develop additional drug candidates or identify additional indications. Due to our limited resources and access to capital, we must prioritize development of a limited number of drug candidates, the choice of which may prove to be wrong and adversely affect our business.

We intend to explore the development of PIPE-791 in indications in addition to IPF and Progressive MS. We recently designated CTX-343, a peripherally restricted LPA1R antagonist, as a drug candidate. We also intend to continue to explore additional drug candidates based on our clinical translational approach and drug development efforts. In each case, we may fail to successfully identify additional indications for PIPE-791, develop CTX-343, or identify viable new drug candidates for clinical development. If we fail to identify additional indications for PIPE-791 or additional potential drug candidates, our business and growth plans could be materially harmed.

Research programs to develop additional indications for our existing drug candidates and to develop additional drug candidates based on our clinical translational approach requires substantial technical, financial, and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications or drug candidates, yet fail to yield results for clinical development for several reasons, including:

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

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

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

We have and may continue to conduct future clinical trials outside of the United States. The FDA and other regulatory authorities or ethics committees may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business and financial condition.

We have previously conducted clinical trials outside of the United States, including our Phase 1 clinical trial of PIPE-307, which was conducted under authorization of the Australian Therapeutic Goods Administration ("TGA") and the National Health and Medical Research Council ("NHMRC") and a Phase 1b PET study of PIPE-307, which was conducted under the authorization of the Research Ethics Committee ("REC") and the MHRA in the United Kingdom. We completed our Phase 1b PET clinical trial for PIPE-307 in RRMS in the United Kingdom, and we intend to conduct our Phase 1b PET clinical trials for PIPE-791 in IPF and Progressive MS in the United Kingdom. We may also conduct additional clinical trials outside the United States in the future. Although the FDA and other foreign regulatory authorities may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by these regulators. For example, non-clinical toxicology studies for our Phase 1b PET study of PIPE-307 were performed in China that were not Good Laboratory Practice ("GLP") compliant and, as China is not a signatory on the Organization for Economic Co-operation and Development ("OECD"), Mutual Acceptance of Data system, a multilateral agreement that allows participating countries to share the results of various non-clinical tests performed using OECD methods and principles, the non-clinical data were not considered acceptable to support the trial. While the Phase 1b was approved on the basis of clinical safety data, the MHRA stated that prior to Marketing Authorization Approval of PIPE-307 in the United Kingdom, an inspection or further evaluation could be triggered. Further, 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 U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. In general, the patient population for any clinical trials conducted outside the United States must be representative of the population for whom we intend to label the drug candidate in the United States. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements for clinical trials. In addition, such trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. Further, the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. In addition, when clinical trials are conducted only at sites outside of the United States, such trials may not be subject to IND review, meaning the FDA may not provide advance comment on the clinical protocols for the trials, and therefore there is an additional potential risk that the FDA could determine that the trial design or protocol for a non-U.S. clinical trial was inadequate, which would likely require an additional clinical trial in order to obtain FDA approval. If the FDA does not accept data from any clinical trials we conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay our drug development plans, which could materially harm our business, financial condition, results of operations and prospects.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- patient monitoring and compliance;
- compliance with foreign manufacturing, customs, shipment and storage requirements (including licensing requirements);
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- tax and local corporate structure considerations.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on the ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. J&J may encounter similar difficulties in enrolling and retaining patients in any clinical trials it initiates for PIPE-307. Patient enrollment and retention in clinical trials depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints;
- the nature of the clinical trial protocol;
- the existing body of safety and efficacy data with respect to the drug candidate;
- the proximity of patients to clinical sites;
- the ability to recruit clinical trial investigators with the appropriate competencies, motivation and experience;
- clinicians' and patients' perceptions as to the potential risks and advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or medical devices that may be approved for the indications being studied;
- the availability of approved products that treat the same indications as the drug candidate being studied;
- the proximity and availability of clinical trial sites for prospective patients;
- the ability to monitor patients adequately during and after treatment;
- competing clinical trials being conducted by other companies or institutions;
- the ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control that may limit patients, principal investigators or staff or clinical site availability, such as uncertain geopolitical conditions or pandemics, such as the recent COVID-19 pandemic.

In addition, any clinical trials we conduct for PIPE-791 or J&J conducts for PIPE-307 will compete with other clinical trials for drug candidates and medical devices that are in the same therapeutic areas as these drug candidates, and this competition could reduce the number and types of patients available to us or J&J, because some patients who might have opted to enroll in any PIPE-791 or PIPE-307 clinical trials may instead opt to enroll in a clinical trial being conducted by a competitor. Furthermore, any negative results we or J&J report in the clinical trials for PIPE-791 and PIPE-307 may make it difficult or impossible to recruit and retain patients in other clinical trials of that same drug candidate. Delays or failures in planned patient enrollment or retention may result in increased costs or program delays, which could have a harmful effect on the continued development of a drug candidate or could render further commercial development impossible.

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

From time to time, we may publicly disclose interim, top-line or preliminary data from the clinical trials we conduct, which is based on a preliminary analysis of then-available data. The final results from these clinical trials and any related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. In addition, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. As a result, the top-line or preliminary results that we report may differ from future results of the same trial, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Top-line or preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until final data is available and published. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular 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.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, the drug candidates we develop may be harmed, which could harm our business, financial condition, results of operations and prospects.

The administration of PIPE-791 and/or PIPE-307 may cause serious adverse events or undesirable side effects, which may halt their clinical development, delay or prevent marketing approval, or, if approved, require them to be taken off the market, include safety warnings, or otherwise limit their sales.

Serious adverse events or undesirable side effects caused by PIPE-791 or PIPE-307 could cause us or J&J, as applicable, or regulatory authorities to interrupt, delay, or halt the clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities for these drug candidates. Results of any clinical trial for PIPE-791 or PIPE-307 could reveal a high and unacceptable severity and prevalence of side effects. If unacceptable side effects arise in the development of any drug candidate, we or J&J, as applicable, the FDA, or the IRBs or IECs at the institutions in which a study is being conducted, or the DSMB, if constituted for a clinical trial, could recommend a suspension or termination of the clinical trial, or the FDA or comparable foreign regulatory authorities could prohibit the further development of or deny approval of a drug candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We or J&J, as applicable, may need to train medical personnel regarding the proper administration protocols for PIPE-791 and PIPE-307 and to understand the potential side effect profiles for these drug candidates. Inadequate training in recognizing or managing the potential side effects of PIPE-791 or PIPE-307 could result in patient injury or death. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Additionally, if PIPE-791, PIPE-307 or any other drug candidate we develop receives marketing approval, and the use of the approved product causes undesirable side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw, or limit approvals of such product, or seek an injunction against its manufacture or distribution, or take other market action in relation to such product;
- regulatory authorities may require a product recall, or we or J&J, as applicable, may decide to initiate a voluntary recall of the product;
- regulatory authorities may require additional warnings on the product's label, such as a "black box" warning or contraindications;
- additional restrictions may be imposed on the marketing of the product or the manufacturing processes for the product or any component thereof;
- we or J&J, as applicable, may be required to implement a Risk Evaluation and Mitigation Strategy ("REMS") or create a medication guide outlining the risks of such side effects for distribution to patients;
- we or J&J, as applicable, may be required to conduct post-market studies or agree to post marketing commitments;
- we or J&J, as applicable, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us or J&J, as applicable, from achieving or maintaining market acceptance of PIPE-791 or PIPE-307, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel 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 other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The market opportunities for the drug candidates we develop, if approved, may be smaller than we anticipate and, as a result, our commercial opportunities may be limited.

We are initially developing PIPE-791 for the treatment of IPF and Progressive MS. We are also developing PIPE-307, in collaboration with J&J. Our projections of the number of eligible patients for each of these indications are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, patient foundations, and market research, and may prove to be incorrect. Further, new sources may reveal a change in the estimated number of eligible patients, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient populations for these programs or our future drug candidates may be limited. For example, even if we obtain FDA approval for PIPE-791 for the treatment of IPF or Progressive MS, the target population approved by the FDA may be more limited than what we currently anticipate. Even if we obtain significant market share for any drug candidate, if approved, if the potential target populations are smaller, we may never achieve profitability without obtaining marketing approval for additional indications.

We have never obtained marketing approval for any drug candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any drug candidate.

We have never obtained marketing approval for any drug candidate. It is possible that the FDA or other foreign regulatory authority may refuse to accept for substantive review any NDAs or similar submission that we submit for PIPE-791 or that J&J may submit for PIPE-307. The FDA may also conclude after review of the data that we or J&J submit that our applications are insufficient to obtain marketing approval for PIPE-791 or PIPE-307, respectively. If the FDA, or other foreign regulatory authority does not accept or approve any NDAs submitted for PIPE-791 or PIPE-307, it may require that we or J&J conduct additional clinical, preclinical, manufacturing validation or other studies and submit that data before it will reconsider the application. Depending on the extent of these or any other required studies, approval of any NDA or similar submission for PIPE-791 or PIPE-307 may be delayed or, in the case of PIPE-791, require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or other foreign regulatory authority to approve any NDAs or similar submission submitted for PIPE-791 or PIPE-307. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing PIPE-791 and J&J from commercializing PIPE-307, and prevent us from generating revenues from these drug candidates to support our continued operations and plans. If any of these outcomes occur, our business, financial condition and results of operations would be significantly harmed.

Even if we obtain FDA approval for a drug candidate in the United States, we may never obtain approval for the drug candidate in any other jurisdiction or commercialize the drug candidate in the United States or in any other jurisdiction, which would limit our ability to realize its full market potential.

In order to market any product in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements regarding safety and efficacy on a country-by-country basis. Approval by the FDA in the United States does not ensure approval by comparable regulatory authorities in other countries or jurisdictions nor does it ensure that we will be able to successfully commercialize such approved drug candidate in the United States or in other jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Further, successful commercialization in the United States does not guarantee successful commercialization in other jurisdictions.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials, which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any drug candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and we will be unable to realize the full market potential of any product we develop.

Even if we obtain regulatory approval for any drug candidate, we will still face extensive and ongoing regulatory requirements and obligations, which may result in significant additional expense, and any drug candidates, if approved, may face future development and regulatory difficulties.

Any drug candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, monitoring, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice ("cGMP") and GCP requirements for any clinical trials conducted post-approval, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and GCP and requirements for any clinical trials that we conduct post-approval.

Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If a drug candidate receives marketing approval, the accompanying label may limit the approved indicated use of the product, which could limit sales of the product. The FDA, or comparable foreign regulators, may also require costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") relating to the promotion of prescription drugs, may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers, or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls or market withdrawals 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; and
- injunctions, consent decrees, or the imposition of civil or criminal penalties.

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

We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. The policies of the FDA and of other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of a drug candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations. Furthermore, noncompliance by us or any collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, may also result in significant financial penalties, which would adversely affect our business.

We may seek a breakthrough therapy and/or orphan drug designation for PIPE-791 or future drug candidates, but we might not receive such designations, and even if we do, we may not maintain such designations, and such designations may not lead to faster development, regulatory review or approval, and will not increase the likelihood that the drug candidate will receive marketing approval.

We may seek a breakthrough therapy and/or orphan drug designation for PIPE-791, or other drug candidates we may 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 existing 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 may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA. We may also seek fast track designation for some of our drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrates the potential to address an unmet medical need, the drug sponsor may apply for fast track designation.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States alone. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the targeted indication, then the drug is entitled to a seven-year period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same drug for the same indication for the exclusivity period except in limited situations, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active moiety and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation.

The FDA has broad discretion whether or not to grant breakthrough therapy, fast track and/or orphan drug designation to any drug candidate. Accordingly, even if we believe that a drug candidate meets the criteria for designation as a breakthrough therapy or orphan drug, the FDA may disagree and instead determine not to make such a designation. Even if we receive breakthrough therapy and/or orphan drug designation, the receipt of such designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a drug candidate qualifies as a breakthrough therapy or orphan drug, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Even if we were to obtain orphan drug designation for a drug candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain a breakthrough therapy, fast track and/or orphan drug designation or admission for any drug candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable drug candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek approval of our drug candidates, where applicable, under the FDA's accelerated approval pathway. This pathway, even if granted for PIPE-791 or any other future drug candidates, may not lead to a faster development, regulatory review or approval process or launch and it does not increase the likelihood that our drug candidates will receive marketing approval in the United States.

We may seek accelerated approval of PIPE-791 and for future drug candidates from the FDA. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we do seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of any drug candidate in our clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a drug candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased market demand for any product; and
- loss of revenue.

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any drug candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our business, financial condition and results of operation, including preventing or limiting the commercialization of any drug candidates we develop.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant operating expenses since inception and anticipate that our operating expenses will continue to significantly increase for the foreseeable future. As a result, we may be unable to sustain profitability, and if we are unable to achieve sustained profitability, the market value of our common stock will likely decline. As of March 31, 2024, we had an accumulated deficit of $83.6 million.

We are a clinical-stage biotechnology company with a limited operating history. To date, we have devoted our efforts to research and development, building our operations, establishing and maintaining our intellectual property portfolio, raising capital, identifying drug candidates for commercialization, conducting preclinical studies and clinical trials and negotiating and entering into the J&J License Agreement. As a result, we have incurred significant operating expenses since our formation. We had a net loss of $8.4 million for the three months ended March 31, 2024. As of March 31, 2024, we had an accumulated deficit of $83.6 million.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential drug candidate will fail to advance through clinical development and eventually gain regulatory approval and become commercially viable. We expect to incur significant additional operating losses for the next several years as we continue to develop PIPE-791 in multiple indications, complete the Phase 2 clinical trial for PIPE-307 in RRMS, and endeavor to advance the development of other drug candidate we identify through our preclinical development efforts, complete preclinical studies and clinical trials, seek regulatory approval and prepare to commercialize any approved product. The costs of advancing drug candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any drug candidate to marketing approval in even a single jurisdiction are substantial.

We expect our operating expenses to increase substantially for the foreseeable future as we:

- complete our current and planned future clinical trials for PIPE-791 in IPF and Progressive MS;
- complete our current clinical trial for PIPE-307 in RRMS;
- expand our product development programs, and develop other drug candidates;
- seek regulatory approvals for PIPE-791, and any other drug candidates we develop;
- secure a commercial manufacturing source and supply chain capacity sufficient to produce commercial quantities of any drug candidate for which we obtain regulatory approval;
- establish a sales, marketing and distribution infrastructure to commercialize any drug candidates for which we may obtain marketing approval;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional clinical, scientific, commercial, operational, financial and management personnel, including personnel to support operations as a public company; and
- acquire or in-license other drug candidates or technologies.

Furthermore, our ability to successfully develop, obtain regulatory approval for and commercialize any drug candidate and generate product revenue is subject to substantial additional risks and uncertainties, as described under "—Risks related to development, clinical testing, and regulatory approval" and "—Risks related to commercialization." As a result, we expect to continue to incur significant operating expenses and negative cash flows for the foreseeable future. These operating expenses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future operating expenses, and any resulting net losses, will depend, in part, on the rate of future growth of our operating expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more drug candidates or if revenues from any product that receives marketing approval or any milestone payments or royalties we receive under the J&J License Agreement are insufficient, we will not be able to maintain profitability. Even if we successfully commercialize one or more of our drug candidates or J&J successfully commercializes PIPE-307, we may continue to incur substantial research and development and other expenses to identify and develop additional drug candidates. We may not be able to achieve sustained profitability or meet outside expectations for our profitability. If we are unable to achieve sustained profitability or to meet outside expectations for our profitability, we will not be able to implement our business plans and the value of our common stock will be materially adversely affected and you may suffer substantial losses in your investment.

We have a limited operating history and the drug candidates we have developed are in the early stages of clinical development, which may make it difficult to evaluate the prospects for our future viability.

We began operations in 2012. Our operations to date have been limited to research and development, building our operations, establishing and maintaining our intellectual property portfolio, raising capital, identifying drug candidates for commercialization, conducting preclinical studies and clinical trials and negotiating and entering into the J&J License Agreement. PIPE-791 and PIPE-307 are in the early stages of clinical development. We have not obtained marketing approval for any drug candidate, and we have not demonstrated the ability to successfully manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will eventually need to transition from a company with a preclinical and early clinical stage focus to a company capable of supporting later stage clinical trials, regulatory approvals and manufacturing and commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, the results of any quarterly or annual period are not necessarily indicative of future operating performance.

We will require significant additional capital to complete the development and commercialization of PIPE-791 and the other drug candidates we select for development.

We expect to spend substantial funds to complete the development of, seek regulatory approvals for and, if approved, commercialize PIPE-791 in IPF and Progressive MS. We will also incur costs to complete our Phase 2 clinical trial for PIPE-307 in RRMS and, could potentially incur significant costs related to PIPE-307 to the extent we have the opportunity and decide to opt-in to fund a portion of all Phase 3 development costs for PIPE-307. We also expect to spend substantial funds to identify and develop new drug candidates based on our clinical translational approach and development efforts. Based on these plans, we will require significant additional capital to complete these development activities and implement our commercialization and business plans, which we may acquire through additional equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. If events or circumstances occur such that we do not obtain additional funding, we may need to delay, reduce or eliminate our product development or future commercialization efforts, which could have a material adverse effect on our business, results of operations or financial condition. Further, if we raise funds through future licensing or other similar commercial arrangements with third parties, similar to the J&J License Agreement, we may be required to relinquish valuable rights to our technology, future revenue streams, research programs or drug candidates or may be required to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development for PIPE-791 in IPF and Progressive MS and any other drug candidates we select for development;
- costs to complete our Phase 2 clinical trial for PIPE-307 in RRMS and potential additional costs related to PIPE-307 to the extent we have the opportunity and decide to opt-in to fund a portion of all Phase 3 development costs for PIPE-307 in any indication;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities, including any additional clinical trials required by the FDA or other comparable foreign regulatory authorities;
- the willingness of the FDA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned clinical trials and preclinical studies, as the basis for review and approval of PIPE-791 in IPF and/or Progressive MS and any other drug candidates we select for development;
- the costs related to maintaining our collaboration with J&J for the development of PIPE-307;
- the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the costs of operating as a public company;
- the cost of making royalty, milestone or other payments under current and any future in-license agreements;
- the extent to which we in-license or acquire other drug candidates, products, technologies or businesses;
- the cost of establishing sales, marketing and distribution capabilities for PIPE-791 and any our drug candidates we develop, if approved; and
- the initiation, progress, and timing of our commercialization of any drug candidate for which we obtain regulatory approval.

Based upon our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities as of the date of this report, will be sufficient to fund our projected operations through at least 12 months from the date of this report. This estimate and our expectation regarding the costs to advance the clinical development of our LPA1R antagonist program, including the completion of our Phase 1b PET imaging trial and Phase 2 clinical trials for our lead drug candidate, PIPE-791, in IPF and Progressive MS, and to complete our existing Phase 2 clinical trial of PIPE-307 for the potential treatment of RRMS and to fund other research and development activities, including the development of our peripherally-restricted LPA1R antagonist drug candidate, CTX-343, are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, or our clinical trials, including our existing and planned clinical trials for PIPE-791, may not achieve the results we expect and may be more expensive, time consuming or difficult to design or implement than we currently anticipate. Our operating runway set forth above also assumes we do not receive any additional payments under our collaboration with J&J for the development of PIPE-307. Changing circumstances, including any unanticipated expenses or development or clinical setbacks, could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and scope of activities associated with successful development of PIPE-791 in each indication and any other drug candidate we develop and associated with J&J's successful development of PIPE-307 and our resulting receipt of milestone or royalty payments is highly uncertain, we are unable to estimate the actual funds we will require for development, obtaining regulatory approval and marketing and commercialization activities for PIPE-791 and the additional drug candidates we select to develop. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of PIPE-791, or any other drug candidate we develop, or potentially discontinue operations. Further, we may not have sufficient funds, if we have the opportunity, to opt-in to fund a portion of all Phase 3 development costs for PIPE-307 in exchange for higher royalty rates.

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

Until such time, if ever, as we can generate substantial revenues, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or other securities convertible, exercisable or exchangeable for our common stock, our existing stockholders' ownershipinterests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, like our J&J License Agreement, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or drug candidates or grant licenses on terms that may not be favorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance research programs, product development activities or drug candidates. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate drug candidate development or future commercialization efforts.

Risks Related to our Existing Collaboration Agreement and any Collaboration Agreements we may enter into in the Future

If the J&J License Agreement does not result in the successful development of PIPE-307, our business, financial condition and results of operations will be harmed.

In February 2023, we entered into the J&J License Agreement with J&J, pursuant to which we received a non-refundable, non-creditable $50.0 million payment in exchange for granting J&J exclusive worldwide rights to develop, manufacture, and commercialize products containing PIPE-307. Under the J&J License Agreement, we are also eligible to receive future milestone payments and tiered royalties in the low-double digit to high-teen percent range on net sales of products containing PIPE-307. J&J is generally responsible for all development, manufacturing, and commercialization activities for PIPE-307. We are conducting, at our own expense, a Phase 2 clinical trial of PIPE-307 for the potential treatment of RRMS, after which J&J may, in its sole discretion, further develop PIPE-307 for such indication. Therefore, even if our Phase 2 clinical trial of PIPE-307 shows positive results, J&J may decide not to further develop PIPE-307 for the potential treatment of RRMS. Further, J&J may prevent or discontinue such clinical trial if it has good faith concerns that such study presents safety risks or could present material adverse effects for the development or commercialization of PIPE-307 generally. Upon J&J deciding to conduct a first Phase 3 clinical trial for a product using PIPE-307, we have an opt-in right to fund a portion of all Phase 3 development costs and other subsequent development costs for PIPE-307 in exchange for increased royalties.

The success of our collaboration with J&J is dependent on J&J successfully completing clinical trials, obtaining regulatory approval and ultimately successfully manufacturing and commercializing PIPE-307. J&J's activities related to PIPE-307, and the benefits of the collaboration to us, are subject to all the risks relating to product development, regulatory approval and commercialization described in "Risks related to development, clinical testing, and regulatory approval" set forth above. In addition, our collaboration with J&J poses additional risks to us, including the following:

- J&J has significant discretion in determining the efforts and resources that it will apply to the collaboration;
- J&J may not perform its obligations as expected;
- the clinical trials conducted as part of the collaboration may not be successful;
- J&J may not pursue development and/or commercialization of PIPE-307 even if it achieves regulatory approval or may elect not to continue or renew development or commercialization of PIPE-307 based on clinical trial results, changes in J&J's strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- J&J may delay clinical trials for PIPE-307, provide insufficient funding for its clinical trials, stop a clinical trial or abandon PIPE-307, repeat or conduct new clinical trials or require a new formulation of PIPE-307 for clinical testing;
- we have limited access to, or are restricted from disclosing, certain information regarding J&J's development and commercialization of PIPE-307 as well as our own Phase 2 clinical trial of PIPE-307 for the potential treatment of RRMS and, consequently, we will have limited ability to inform our stockholders about the status or results of the clinical development of PIPE-307, including our existing Phase 2 clinical trial of PIPE-307 and any trial that J&J conducts with PIPE-307;
- J&J could independently develop, or develop with third parties, products that compete directly or indirectly with PIPE-307 if it believes that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than PIPE-307;
- J&J may view any drug candidates we develop by ourselves, or in collaboration with another third party, as competitive with its other drug candidates or products, which may cause J&J to cease to devote resources to the development and commercialization of PIPE-307;
- even if it obtains marketing approval for PIPE-307, J&J may not commit sufficient resources to the marketing, distribution and commercialization of PIPE-307;
- disagreements with J&J, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any programs or drug candidates, may cause delays or termination of the research, development, manufacture or commercialization of PIPE-307, may lead to additional responsibilities for us with respect to the development of PIPE-307 or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- J&J may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with J&J with respect to the ownership of intellectual property developed pursuant to the collaboration;
- J&J may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- J&J may terminate the collaboration for convenience and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of PIPE-307.

If our collaboration with J&J does not result in the successful development and commercialization of PIPE-307, or if J&J terminates its agreement with us, we may not receive any future milestone or royalty payments under the collaboration. If we do not receive the payments we expect under our collaboration with J&J, our business, financial condition and operating results will be adversely impacted and we may need additional resources to continue to develop PIPE-791 and our other drug candidates.

We may not recognize the financial and other benefits of any additional collaborations or strategic alliances that we may enter into in the future for the development and commercialization of our drug candidates.

The clinical trial and regulatory approval process and the potential manufacturing and commercialization of PIPE-791 in multiple indications and the other drug candidates we select for development will require the investment of substantial additional capital. In addition to the J&J License Agreement, we may seek and form additional strategic alliances, or create joint ventures or collaborations or enter into acquisitions or additional licensing arrangements with third parties that we believe will help to accelerate or augment our clinical trial, regulatory approval, manufacturing and commercialization efforts with respect to PIPE-791 and any future drug candidates that we elect to develop. These transactions can entail numerous operational and financial risks, and we cannot be certain that we will achieve the financial and other benefits that led us to enter into such arrangements.

We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish future strategic partnerships or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the following:

- the design or results of clinical trials for the drug candidate;
- the likelihood of approval of the drug candidate by the FDA or comparable foreign regulatory authorities;
- the potential market for the drug candidate;
- the costs and complexities of manufacturing and delivering such drug candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of, or the intellectual protection for, the drug candidate, which can exist if there is a challenge to such ownership or intellectual property rights without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. We may also be restricted under any license agreements from entering into agreements on certain terms, or at all, with potential collaborators.

As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate product revenue without collaborations. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

Even if we do enter into a collaboration agreement for PIPE-791 or another drug candidate we select for development, we may not recognize the potential financial and other benefits of the collaboration. When we collaborate with a third party, we relinquish some or all of the control of the clinical trial and regulatory approval process and the potential manufacturing and commercialization of the drug candidate. In addition, all of the risks relating to product development, regulatory approval and commercialization summarized and described in this report also apply to the activities of our collaborators. Further, the collaborator may terminate its agreement with us. As a result, a collaboration may not result in the successful development and commercialization of our drug candidate, and we may not receive any milestone or royalty payments under the collaboration. If we do not receive the payments we expect under these agreements, our development of drug candidates could be delayed and we may need additional resources to develop our drug candidates.

We may seek to grow our business through in-licensing transactions or otherwise by acquiring drug candidates or complementary products, technologies or businesses. The failure to properly identify these drug candidates, products, technologies or businesses, as well as the failure to successfully complete transactions or to integrate any such drug candidates, products, technologies or businesses that we do in-license or acquire with our existing business, could harm our business, financial condition and operating results.

In the future, we may enter into transactions to in-license or acquire rights to drug candidates or to complementary products or technologies, or to acquire other businesses. Even if we do identify suitable candidates, we may not be able to enter into such transactions on favorable terms, or at all. Any such in-licenses or acquisitions of drug candidates may not result in our ability to successfully develop and obtain regulatory approval for such drug candidates. In addition, any such transactions may not strengthen our financial position or our competitive position or commercialization efforts, and these transactions may be viewed negatively by analysts, investors, customers, or other third parties with whom we have relationships. We may decide to use our available cash resources or incur debt in connection with an in-licensing or acquisition transaction, be required to make significant milestone or royalty payments, or issue our common stock or other equity securities as consideration for the transaction, which would reduce our operating runway or the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the in-licensed or acquired drug candidate, product technology or the acquired business that are not covered adequately by the indemnification we may obtain from the licensor or seller of such assets or business. In addition, we may not be able to successfully integrate any acquired drug candidates, personnel, technologies, and operations into our existing business in an effective, timely, and nondisruptive manner. Such transactions may also divert management attention from day-to-day responsibilities, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future in-licenses or acquisitions or the effect that any such transactions might have on our business, financial condition and operating results.

Risks Related to our Intellectual Property

If we are unable to obtain, maintain and enforce intellectual property protection for our technology and drug candidates or if the scope of the intellectual property protection we obtain is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize and generate revenues from our drug candidates may be adversely affected.

Our success depends in large part on our ability to obtain, maintain and enforce intellectual property protection for the technology and drug candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and drug candidates that are important to our business and by in-licensing intellectual property related to such technologies and drug candidates. If we are unable to obtain or maintain patent protection with respect to any proprietary technology or drug candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, defend, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain, enforce, and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents, and applications may not be prepared, filed, prosecuted, maintained, defended, and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to our drug candidates. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability, and commercial value of our owned and in-licensed patent rights are uncertain. Moreover, our owned and in-licensed pending and future patent applications may not result in patents being issued which protect our technology and drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend, and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value or narrow the scope of our patent rights.

Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office ("USPTO") or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and drug candidates.

Patent terms may be inadequate to protect our competitive position on our drug candidates for an adequate amount of time.

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

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any drug candidates we may develop, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our drug candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those drug candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations, and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a United States patent covering any of our drug candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”). We may be unable to obtain patents covering our drug candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our drug candidates is approved and a patent covering that drug candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such drug candidate.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (“Leahy-Smith Act”) could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement, or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution, and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected drug candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, drug candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and drug candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the drug candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, or delay or prohibit the further development or commercialization of, one or more drug candidates that rely on such agreements.

Although we are not currently involved in any litigation, we may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property. As a result, we may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable.

An adverse result in any such proceeding could put one or more of our owned patents at risk of being invalidated or interpreted narrowly and could put any of our owned patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned patents do not cover such technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations, and prospects.

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

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

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and drug candidates, including interference proceedings, post grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or drug candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our drug candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and drug candidates and their uses, or we may incorrectly conclude that third party intellectual property is invalid or that our activities and drug candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and drug candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the discovery, use or manufacture of the drug candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the drug candidates that we may develop may be found to infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the drug candidates that we may develop, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such drug candidate unless we obtained a license under the applicable patents, or until such patents expire.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the drug candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and drug candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our customers or collaborators. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our drug candidates, seek new regulatory approvals, and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

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

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms, and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications covering our drug candidates, it would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Filing, prosecuting, and defending patents on drug candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect, to the same extent or at all, inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets, or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers, or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including potential competitors. Although we try to ensure that our employees, consultants, and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

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

In addition to seeking patents for some of our technology and drug candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our drug candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable drug candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or drug candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our drug candidates on a substantial scale, if approved, before the relevant patents that we own, or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to our Dependence on Third Parties

We currently rely on third-party CMOs for the production of clinical supplies of PIPE-791 and PIPE-307 and we intend to rely on CMOs for our future drug candidates, as well as to supply the raw materials necessary to produce our drug candidates. We may elect to continue to rely on CMOs for the production of commercial supplies of PIPE-791, if approved. Our dependence on CMOs may impair our development of drug candidates and may impair their commercialization, which would adversely impact our business and financial position.

We do not own facilities to manufacture PIPE-791, PIPE-307 or any of our drug candidates in development. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials of PIPE-791 and any other drug candidates we develop. We have relied on CMOs to supply the clinical trial materials for our Phase 2 clinical trial of PIPE-307 and, going forward, J&J may continue to rely on CMOs for the future development, manufacture and potential commercialization of PIPE-307. We intend to continue to rely on CMOs for the production of commercial supplies of PIPE-791, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our drug candidates ourselves. If any CMO we engage is unable to provide sufficient supply of any drug candidate we develop, we may be unable to arrange for an alternative supply or to do so on commercially reasonable terms or in a timely manner, which could delay any clinical trials, the commercial launch of a drug candidate, if approved, or, regarding any commercial supply, result in a shortage in supply that could negatively impact our revenues. Transitioning to a new CMO for a drug candidate is time consuming and costly. We have identified, but have not contracted with, other CMOs as back-up for the manufacture and supply of PIPE-791. As a result, if the CMO currently involved in the manufacture and supply of PIPE-791 experiences a delay or disruption, we may not have sufficient quantities of PIPE-791 for our clinical trials and may not be able to transition to a new CMO in a timely or cost- effective manner, or at all, which would negatively impact our ability to develop, complete our planned clinical trials for PIPE-791.

Similarly, we contract for the supply of the active pharmaceutical ingredients ("APIs") and other raw materials necessary to produce PIPE-791. We currently intend to contract in the future for the supply of these APIs and other raw materials for any other drug candidate we develop. Supplies of our APIs or other raw materials could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable time frame, at an acceptable cost, or at all. In addition, a disruption in the supply of any required API or other raw material could delay the commencement of a planned clinical trial or the delay the commercial launch of a drug candidate, if approved, or result in a shortage in supply, which would impair our ability to generate revenues. Growth in the costs and expenses of our APIs or other raw materials may also impair our ability to cost-effectively manufacture a drug candidate. In addition, there may be a limited number of suppliers for the APIs or other raw materials that we may use to manufacture a drug candidate, and we cannot be certain that we will be able to engage such suppliers in a timely manner or at all. If we are unable to do so, clinical development of a drug candidate, commercialization for any approved product, or our business could be adversely affected.

The facilities used to manufacture the drug candidates we develop, as well as the included APIs, must be inspected by the FDA and comparable foreign regulatory authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be dependent on, our CMOs for compliance with cGMP requirements for the manufacture of a drug candidate. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance, and qualified personnel, and we were not involved in developing our CMOs' policies and procedures. As a result, we are subject to the risk that a drug candidate may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of the drug candidate in clinical trials, or for commercial distribution of the drug candidate, if approved.

If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of the drug candidates we develop or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and planned clinical trials and significantly impact our ability to develop, obtain regulatory approval for, or commercialize such drug candidates, if approved. In addition, any failure to achieve and maintain compliance with laws, regulations, and standards related to manufacturing could subject us to risks, including the risk that we may have to suspend the manufacture of a drug candidate, that obtained approvals could be revoked, and that the FDA or another governmental regulatory authority may take enforcement actions, including untitled letters, warning letters, seizures, injunctions, or product recalls. Foreign CMOs may be subject to U.S. legislation, including the proposed BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to manufacture our drug candidates. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of the drug candidate to complete the clinical trial, any significant delay in the supply of the drug candidate or the raw materials needed to produce the drug candidate, could adversely affect our business in a number of ways, including but not limited to:

- an inability to initiate or continue clinical trials of our drug candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our drug candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- economic loss and additional costs resulting from starting materials, intermediates, API or drug product that cannot be used in clinical trials or for other purposes;
- requirements to cease development or to recall batches of our drug candidates; and
- in the event of approval to market and commercialize our drug candidates, an inability to meet commercial demands for our product or any other future drug candidates.

As part of their manufacture of our drug candidates, our CMOs and third-party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, complete our planned clinical trials, obtain regulatory approval for, or commercialize a drug candidate, if approved.

We rely on third parties to conduct our ongoing clinical trials of PIPE-791 and PIPE-307 and expect to rely on third parties to conduct future clinical trials of PIPE-791 and any other drug candidates that we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize the drug candidates we develop and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for the drug candidates we develop. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to these drug candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our drug candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our drug candidates, or if the data prove to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

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

We, our principal investigators and our CROs are required to comply with regulations, including GCPs for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA and similar regulatory authorities in foreign countries. These regulatory authorities enforce GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or similar foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, these regulatory authorities will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with drug candidates produced under cGMP regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we designed our first-in-human clinical trials of PIPE-791 and PIPE-307, and intend to design the future clinical trials for the drug candidates that we develop, we expect that CROs will conduct all of our clinical trials. J&J will be responsible for designing any future clinical trials of PIPE-307. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

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

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

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

We intend to rely on CROs, and other third parties to conduct our preclinical studies. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We rely, and will continue to rely, on CROs, CRO-contracted vendors, to conduct preclinical studies on the drug candidates we develop. Our reliance on CROs for preclinical development activities limits our control over these activities and we were not involved in developing our CRO's policies and procedures, but we remain responsible for ensuring that each of our preclinical studies is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards.

We and our CROs will be required to comply with the GLP requirements for our preclinical studies, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Our CROs are not our employees, and we do not control whether they devote sufficient time and resources to our preclinical studies. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting preclinical studies, clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, or fail to meet expected deadlines, or if the quality or accuracy of the preclinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for any other reason, our ability to generate the preclinical data to advance the development of our drug candidates will be harmed.

If our relationship with any CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired preclinical development timelines. Though we intend to carefully manage our relationships with our CROs, 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 an adverse impact on our business, financial condition, and prospects.

Our third-party manufacturers may be unable to successfully scale-up manufacturing of our drug candidates in sufficient quality and quantity, which could delay or prevent us from developing our drug candidates and commercializing approved products, if any.

In order to conduct clinical trials for the drug candidates we are developing, we will need to manufacture them in large quantities. Quality issues may arise during scale-up activities. Our reliance on a limited number of manufacturers, the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required licensure, or commercialization of our drug candidates, cause us to incur higher costs and prevent us from commercializing our drug candidates successfully. Furthermore, if our manufacturing partners fail to deliver the required commercial quality and quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement manufacturer capable of production in a timely manner at a substantially equivalent cost, then testing and clinical trials of that drug candidate may be delayed or infeasible, and regulatory licensure or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Manufacturing of the API for PIPE-791 takes place in China, through a sole third-party manufacturer. A significant disruption in the operation of this manufacturer could materially adversely affect our business, financial condition and results of operations.

We currently contract manufacturing operations to third parties, and the manufacturing of the API for PIPE-791 is completed by a third party located in China. Any disruption in production or inability of this manufacturer to produce adequate quantities to meet our needs could impair our ability to further development of PIPE-791. Furthermore, since this third-party manufacturer is located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. Any of these matters could materially and adversely delay our development efforts and affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding the drug candidates we are studying in our clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization 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.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization of the drug candidates we develop, could engage in misconduct, including intentional, reckless, or negligent conduct or unauthorized activities that violate applicable laws, rules, and regulations including: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete, and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse, and other healthcare laws and regulations; or laws that require the reporting of true, complete, and accurate financial information and data. Specifically, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these or other laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us or them and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Recent and future changes in healthcare legislation and regulations may increase the difficulty and cost to obtain marketing approval for a drug candidate, increase the costs to commercialize an approved product, and adversely affect the price set for such product.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact the future results of our operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels with the stated objective to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Provisions of the ACA with importance to the biotechnology and pharmaceutical industries include, among others:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- the requirement of a distinct calculation for rebates owed by manufacturers under the Medicaid Drug Rebate Program for drugs and biologics that are inhaled, infused, instilled, implanted, or injected; and
- a Medicare Part D coverage gap discount program, under which manufacturers must agree to offer certain discounts on applicable branded drugs to eligible beneficiaries during their coverage gap period.

The ACA and its implementation continue to evolve as a result of legislative, administrative, and judicial developments. Further changes remain possible, which may potentially negatively affect pricing, coverage, or reimbursement for PIPE-791 and/or PIPE-307.

In addition to the ACA, U.S. governments continue to seek to adopt healthcare policies and reforms intended to curb healthcare costs, such as federal or state controls on payment for drugs (including under Medicare, Medicaid, and commercial health plans). For example, the Budget Control Act of 2011 resulted in aggregate reductions, or sequestration, of Medicare payments to providers. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, adjusted Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

More recently, the Inflation Reduction Act of 2022 ("IRA") requires, among other things, the U.S. Secretary of the Department of Health and Human Services ("HHS") to negotiate, with respect to Medicare units and subject to a specified cap, called the Maximum Fair Price, the price of a set number of certain high spend Medicare Part B and D drugs and biologicals per year, with prices taking effect starting in 2026. Though the IRA explicitly excludes from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition, drugs with multiple orphan designations are not explicitly excluded from drug price negotiation, which may affect the profitability of pursing multiple indications for an orphan drug. Any failure to comply with requirements under the drug price negotiation program could subject us to an excise tax and/or a civil monetary penalty. The IRA also makes several changes to the Medicare Part D benefit, including capping patient out-of-pocket spending at $2,000 beginning in 2025, while imposing new discount obligations for pharmaceutical manufacturers and payors, which could negatively affect our business and financial condition. If we are not in compliance with obligations under the Medicare Part D benefit redesign, we could be subject to civil monetary penalties. In addition, the IRA establishes Medicare Part B and Part D inflation rebate schemes, under which manufacturers will owe rebates to Medicare if, generally speaking, the average sales price of a Part B drug, or the average manufacturer price of a Part D drug, increases faster than the pace of inflation. The failure to timely pay an inflation rebate may result in a civil monetary penalty. Since the IRA was enacted, the Centers for Medicare and Medicaid Services ("CMS") has taken various steps to implement the drug pricing provisions of the law. This includes releasing a list of Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA for the time period of October 1, 2023 to December 31, 2023 in September 2023; on June 30, 2023, issuing guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026; and, on August 29, 2023, releasing the initial list of 10 drugs subject to price negotiations. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry (including orphan drug development), several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the HHS, the Secretary of HHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. The IRA and any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our future revenues and results of operations.

Individual states in the United States have also become increasingly aggressive in seeking to pass legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Such measures could harm our business, results of operations, financial condition, and prospects. For example, an emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost". We expect that additional state reform measures will be adopted in the future, any of which could limit the amounts that state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for our drug candidates, or additional pricing pressures.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our drug candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers, and others will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our drug candidates, as well as our customer support and physician consulting arrangements. Such laws include:

- the U.S. federal Anti-Kickback Statute ("AKS"), a criminal law which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or anything of value), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, arrangement, or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs (such as Medicare and Medicaid). A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers or their agents and prescribers, purchasers and formulary or benefit managers, among other parties;
- the U.S. federal false claims and civil monetary penalties laws, including the False Claims Act ("FCA"), which prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds; knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. In addition, any claims submitted as a result of a violation of the AKS constitute false claims and are subject to enforcement under the FCA. Pharmaceutical manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA can be enforced by the U.S. Department of Justice or through whistleblower or qui tam actions filed by private citizens on behalf of the federal government;
- certain criminal provisions enacted as part of the U.S. federal Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters, regardless of the payor (e.g., public or private). Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA and the respective implementing regulations, which impose, among other things, specified requirements relating to privacy, security and breaches of individually identifiable health information by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the creation, receipt, maintenance, or transmission of protected health information. HIPAA provides for criminal penalties, as well as civil monetary penalties, and is enforced by the Office of Civil Rights within the HHS as well as state attorneys general, which can file civil actions for damages or injunctions in federal courts and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. federal Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, along with others, to track and report annually to the government information related to certain payments and other transfers of value to U.S.-licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by certain physicians and their immediate family members in the manufacturer;
- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial monetary penalties against an entity, such as a pharmaceutical manufacturer, that engage in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the AKS; or (4) failing to report and return a known overpayment;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information that require the tracking of gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the California Consumer Privacy Act ("CCPA"), as amended by the California Privacy Rights Act ("CPRA"), establishes certain requirements for data use and sharing transparency and provides California consumers (as defined in the law) certain rights concerning the use, disclosure, and retention of their personal data. Such rights include rights to access and delete personal information, opt out of certain personal information sharing, and receive detailed information about how personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches—involving certain types of personal information—that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Numerous other states, such as Virginia, Colorado, Utah, and Connecticut, have enacted privacy laws similar to the CCPA, and some states, like Washington, have enacted health privacy specific laws that grant heightened rights with respect to health information;
- similar healthcare laws and regulations in the European Union, or EU, and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information, such as, where applicable, the General Data Protection Regulation, including as implemented in the UK, or GDPR, which imposes obligations and restrictions on the processing of personal data relating to individuals located in the European Union ("EU") and the European Economic Area ("EEA") (including health data); and
- laws and regulations prohibiting bribery and corruption such as the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with healthcare providers, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to actions including the imposition of civil, criminal, and administrative penalties, damages (potentially up to treble damages), disgorgement, monetary fines, exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be adversely affected.

Any clinical trial programs, marketing, or research collaborations in the European Economic Area will subject us to the GDPR.

The GDPR applies to companies established in the EEA, as well as to companies that are not established in the EEA and which, *inter alia*, collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA. If we conduct clinical trial programs in the EEA (whether the trials are conducted directly by us or through a clinical vendor or collaborator), or enter into research collaborations involving the monitoring of individuals in the EEA, or market our products to individuals in the EEA, we will be subject to the GDPR. The GDPR puts in place stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data (or reliance on another appropriate legal basis), the provision of robust and detailed disclosures to individuals about how personal data is collected and processed (in a concise, intelligible and easily accessible form), a comprehensive individual data rights regime (including access, erasure, objection, restriction, rectification and portability), maintaining a record of data processing, data export restrictions governing transfers of data from the EEA, short timelines for certain data breach notifications to be given to data protection regulators or supervisory authorities (and in certain cases, affected individuals), and limitations on retention of personal data. The GDPR also puts in place increased requirements pertaining to health data and other special categories of personal data, and includes within scope, pseudonymized (i.e., key-coded) data. Further, the GDPR provides that EEA member states may establish their own laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use, and share such data and/or could cause our costs to increase. In addition, there are certain obligations if we contract third-party processors in connection with the processing of personal data. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data, or fines of up to 20 million Euros or up to 4% of our total worldwide annual revenue of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, including class-action type litigation, negative publicity, reputational harm and a potential loss of business and goodwill. Additionally, following the United Kingdom's withdrawal from the European Union, we will have to comply with the GDPR and the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million/ £17.5 million, respectively, or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains subject to change, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

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

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as Trade Laws, prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Exports of our products are further subject to export controls and sanctions laws and regulations imposed by the U.S. government and administered by the U.S. Departments of State, Commerce, and Treasury. U.S. export control laws may require a license or other authorization to export products to certain destinations and end users. In addition, U.S. economic sanctions laws include restrictions or prohibitions on engaging in any transactions or dealings, including receiving investment or financing from, or engaging in the sale or supply of products and services to, U.S. sanctioned countries, governments, persons and entities.

Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any changes in Trade Laws could result in a decreased ability to export or sell our solutions to, existing or potential customers with international operations. Future changes in Trade Laws and enforcement could also result in increased compliance requirements and related costs which could materially adversely affect our business, results of operations, financial condition and/or cash flows.

Risks Related to our Employees, Managing our Growth and our Operations

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

We are highly dependent on Carmine Stengone, our President and Chief Executive Officer, Daniel Lorrain, Ph.D., our Chief Scientific Officer, Stephen Huhn, M.D., our Chief Medical Officer and Senior Vice President of Clinical Development, Peter Slover, our Chief Financial Officer, as well as the other principal members of our management, scientific, and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time. Further, we do not maintain "key man" life insurance on our executive officers.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize drug candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by other companies or organizations and may have commitments that limit their availability. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our drug candidates will be limited.

We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our business and operations could be materially and adversely affected in the event of system failures.

Despite the implementation of security measures, our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters (including earthquakes or fires), terrorism, war, PHEs, and telecommunication and electrical failures. While we do not believe that we have experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our or their operations, it could result in delays and/or material disruptions of our research and development programs. For example, the loss of preclinical or clinical trial data from ongoing, or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, and the development of our drug candidates could be delayed.

Our proprietary or confidential information may be lost, or we may suffer security breaches.

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data. In the ordinary course of our business, we and third parties with which we have relationships will continue to collect and store sensitive data, including clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance, or other disruptions. A number of proposed and enacted federal, state and international laws and regulations obligate companies to notify regulators and/or individuals of security breaches, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors, or other organizations with which we have formed strategic relationships. Although, to our knowledge, neither we nor any such third parties have experienced any material security breach, and even though we may have contractual protections with such third parties, any such breach could compromise our or their networks and the information stored therein could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws including those that protect the privacy of personal information, and significant costs, including regulatory penalties, fines, and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation, and cause a loss of confidence in us and our or such third parties' ability to conduct clinical trials, which could adversely affect our reputation, delay the clinical development of our drug candidates and materially and adversely affect our business.

Risks Related to Commercialization

We face significant competition from biotechnology, pharmaceutical, and medical device companies, and our operating results will suffer if we fail to compete effectively and in a timely manner.

The biotechnology, pharmaceutical, and medical device industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If a drug candidate we develop is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies and early-stage companies, particularly if the early-stage company has a collaborative arrangement with a large and established company.

In addition, we face competition with respect to our current drug candidates and will face competition with respect to any other drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of drug candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

PIPE-791 for IPF

While there is no pharmacological cure for IPF, there are two FDA-approved therapies to treat the disease: pirfenidone (Esbriet, marketed by Genentech/Roche) and nintedanib (Ofev, marketed by Boehringer Ingelheim). We are also aware of LPA1R targeted drug candidates in development for IPF by Bristol-Meyers Squibb, AbbVie Inc., Horizon Therapeutics plc, and Structure Therapeutics Inc. In addition, there are a number of companies developing drug candidates for IPF utilizing approaches with different mechanisms of action, including but not limited to Roche Holding AG, Boehringer Ingelheim, United Therapeutics Corporation, Pliant Therapeutics, RedX Pharma, and Endeavor Biomedicines.

PIPE-791 for Progressive MS

While there are a number of MS medications approved by the FDA for the “active” form of SPMS, no FDA-approved drugs carry a specific indication for Progressive MS. Mitoxantrone (Novantrone®, marketed by Serono) is approved for secondary (chronic) Progressive MS and ocrelizumab (Ocrevus®, marketed by Genentech/Roche) is approved for PPMS.

PIPE-307 for Depression

There are numerous approved therapies for depression, including antidepressant drugs such as selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, antipsychotics and mood stabilizers. A number of these approved therapies are offered as generics.

PIPE-307 for RRMS

We are aware of over 20 disease-modifying treatments that suppress inflammatory injury and decrease the rate of annual relapses. However, to our knowledge, none of these approved therapies, including any generics, effectively promote remyelination to mitigate the progressive disability associated with chronic demyelination.

Many of the companies that we compete against or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, we cannot predict whether our current competitive advantages, such as our ability to develop selective compounds targeting challenging molecular pathways, will remain in place in the future. If these or other barriers to entry do not remain in place, other companies may be able to more directly or effectively compete with us.

Further, competition could render any drug candidate we develop obsolete, less competitive, or uneconomical. Our competitors may, among other things:

- develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- have significantly greater name recognition and financial, manufacturing, marketing, product development, technical, and human resources than we do, with mergers and acquisitions in the biotechnology, pharmaceutical, and medical device industries resulting in even more resources being concentrated in our competitors;
- more effectively recruit and retain qualified scientific and management personnel;
- more effectively establish clinical trial sites and patient registration;
- better protect their patents and intellectual property or acquire technologies that are complementary to, or necessary for, our programs;
- implement more effective approaches to sales, marketing, pricing, coverage, and reimbursement; or
- form more advantageous strategic alliances or collaborations.

If we are not able to effectively compete for any of the foregoing reasons, our business, financial condition and results of operations will be materially harmed.

Even if PIPE-791 or PIPE-307 receives marketing approval in an indication, it may fail to achieve market acceptance by physicians, patients, third-party payors, or others in the medical community necessary for commercial success.

Even if PIPE-791 or PIPE-307 receives marketing approval for an indication, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or royalties to become profitable. The degree of market acceptance of PIPE-791 or PIPE-307, if approved, will depend on several factors, including, but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the ability to offer a product for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product together with other medications.

Because we expect sales of PIPE-791 or PIPE-307, if approved, to generate substantially all our revenues for the foreseeable future, the failure of these drug candidates to find market acceptance would harm our business and could require us to seek additional financing.

We have no sales, marketing or distribution capabilities or experience. If we are unable to establish sales and marketing capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing PIPE-791, even if approved.

We have no sales, marketing or distribution capabilities or experience. In order to market and successfully commercialize PIPE-791, even if approved, we must build our sales and marketing capabilities or enter into collaborations with third parties for these services. We currently have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. We currently intend to directly market and commercialize PIPE-791, if it is approved, in the United States by developing our own sales and marketing force. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, train, retain, and appropriately incentivize a sufficient number of qualified individuals, generate sufficient sales leads and provide our sales and marketing team with adequate access to physicians who may prescribe our product, effectively manage a geographically dispersed sales and marketing team, and other unforeseen costs and expenses. Any failure or delay in developing PIPE-791 that affects the expected timing for its commercialization or results in its failure to be commercialized could result in us having prematurely or unnecessarily incurred costly commercialization expenses.

We may also enter into collaborations for the sales and marketing of PIPE-791, if approved, especially in jurisdictions outside the United States. To the extent that we depend on collaborators for sales and marketing activities, any revenues we receive will depend upon the success of those collaborators' sales and marketing teams and the collaborators' prioritization of our product and compliance with applicable regulatory requirements, and there can be no assurance that the collaborators' efforts will be successful.

If we are unable to build our own sales and marketing team or enter into collaborations for the commercialization of PIPE-791, if approved, we may be forced to delay the commercialization of PIPE-791 or reduce the scope of our sales or marketing activities, which would have an adverse effect on our business, results of operation and prospects.

The successful commercialization of PIPE-791 or PIPE-307 will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies for such drug candidates. Failure to obtain or maintain coverage and adequate reimbursement for PIPE-791 or PIPE-307, even if approved, could limit our or J&J's ability to market these products and decrease the revenue we generate or the royalties we receive.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications. The ability to achieve acceptable levels of coverage and reimbursement for PIPE-791 and PIPE-307, if approved, by governmental authorities, private health insurers and other organizations will influence our ability and J&J's ability, respectively to successfully commercialize these drug candidates. Obtaining adequate coverage and reimbursement for a drug candidate that is administered under the supervision of a physician, which is what we anticipate for both PIPE-791 and PIPE-307, may be particularly difficult because of the higher prices associated with such products. As a result, availability of coverage and reimbursement by payors is highly uncertain. A decision by a third-party payor not to cover or separately reimburse a product could reduce physician utilization of the product once approved. Assuming PIPE-791 and PIPE-307 obtain coverage by third-party payors, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for PIPE-791 or PIPE-307, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and Congress has introduced several proposals related to drug pricing, as discussed above. Many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. Even if PIPE-791 or PIPE-307 offer improved efficacy, pricing of existing drugs may limit the amount we and J&J, respectively, can charge for these products. Payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable a satisfactory return on investment. If reimbursement is not available for PIPE-791 or PIPE-307, or is available only at limited levels, neither we nor J&J may be able to successfully commercialize these drug candidates. Additionally, revenues we ultimately receive from PIPE-791 or PIPE-307 will also depend on what, if any, proposals related to drug pricing may be implemented and, if implemented, when they might take effect.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for PIPE-791 and PIPE-307.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor, and one third-party payor's decision to cover a product does not ensure that other payors will also provide similar coverage. Additionally, the process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the price of such product or establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, the determination of coverage and reimbursement is often a time-consuming and costly process that will require the seller to provide scientific and clinical support for the use of the drug candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment to support the commercialization of PIPE-791 or PIPE-307. We expect that any commercialization of PIPE-791 and PIPE-307 will be subject to pricing pressures due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative, administrative, or regulatory changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Any commercialization of PIPE-791 and PIPE-307 may also be subject to extensive governmental price controls and other market regulations outside of the United States. The increasing emphasis on cost-containment initiatives in other countries have and, we believe, will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we or J&J are able to charge for PIPE-791 and PIPE-307, respectively. Accordingly, in markets outside the United States, the reimbursement for PIPE-791 and PIPE-307 may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for an approved products could limit the ability to market the product and decrease the revenues we ultimately receive.

The pricing, coverage and reimbursement for PIPE-791, if approved, must be adequate to support the commercial infrastructure required to market and sell PIPE-791. Our per-patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. However, sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a product does not ensure that other payors will also provide coverage for the product. As a result, we have no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. For products administered under the supervision of a physician in a physician office setting, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, we may not be guaranteed separate reimbursement for the product itself or the treatment or procedure in which the product is used, which may impact physician utilization.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products such as ours. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit or delay sales of any of our future products. Decreases in third-party reimbursement or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for any of our future products.

In international markets, reimbursement and healthcare payment are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries has and will continue to put pressure on the pricing and usage of our drug candidates. In many countries, the prices of medicinal products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medical devices under such systems are substantially lower than in the U.S. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability of manufacturers to sell products profitably. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, if we participate in these programs, we could be subject to additional rebate requirements, penalties, or other sanctions, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

Under the Medicaid Drug Rebate program, a participating manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by the state Medicaid program as a condition of having federal funds being made available for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. If we fail to pay the required rebate amount or report pricing data on a timely basis, we may be subject to civil monetary penalties and/or termination from the Medicaid Drug Rebate program. Additionally, civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing or product information to the government, if we fail to submit the required pricing data on a timely basis, or if we misclassify or misreport product information. CMS could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Federal law requires that a manufacturer also participate in the 340B Drug Pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to specified "covered entities," including community health centers and other entities that receive certain federal grants, as well as certain hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated based on the information reported under the Medicaid Drug Rebate program. If we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price, we could be subject to significant civil monetary penalties and/or such failure also could be grounds for the Health Resources and Services Administration to terminate our agreement to participate in the 340B program, in which case our covered outpatient drugs would no longer be eligible for federal payment under the Medicaid or Medicare Part B program.

Federal law also requires that manufacturers report to CMS, on a quarterly basis, average sales price information for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate average sales price based on a statutorily defined formula as well as regulations and guidance. CMS uses the reported information to determine payment rates for drugs under Medicare Part B. If we are found to have made a misrepresentation in the reporting of our average sales price, we may be subject to civil monetary penalties. In addition, if we fail to provide timely information or knowingly provide false information, then we may also be subject to significant civil monetary penalties.

In addition, starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. A failure to pay refunds for discarded drugs under the discarded drug refund program could be subject us to civil monetary penalties of 125 percent of the refund amount.

Pricing and rebate calculations are complex, vary across products and programs, and are often subject to interpretation by the manufacturer, governmental agencies, and courts. A manufacturer that becomes aware that its Medicaid reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, is obligated to resubmit corrected data up to three years after those data originally were due. Restatements and recalculations increase the costs for complying with the laws and policies governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. They also may affect the 340B ceiling price and therefore liability under the 340B program.

In order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs ("VA"), Department of Defense ("DoD"), Public Health Service, and Coast Guard (the Big Four agencies), and certain federal grantees, a manufacturer is required to participate in the VA Federal Supply Schedule ("") pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price ("FCP"), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the "non-federal average manufacturer price" (the "Non FAMP"), which the manufacturer calculates and reports to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

Under Section 703 of the National Defense Authorization Act for FY 2008, the manufacturer is required to pay quarterly rebates to DoD on utilization of its innovator products that are dispensed through DoD's Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non FAMP and FCP for the calendar year that the product was dispensed. A manufacturer that overcharges the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations.

Additional U.S. federal healthcare reform measures may be implemented in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

A variety of risks associated with operating internationally could materially adversely affect our business.

Our business strategy includes potentially expanding internationally if PIPE-791 receives regulatory approval. Doing business internationally involves several risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, economic sanctions laws and regulations, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of PIPE-791 in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, PHEs, boycotts, curtailment of trade, and other business restrictions;
- certain expenses, including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA, its books and records provisions, or its anti-bribery provisions, as well as other applicable laws and regulations prohibiting bribery and corruption.

Any of these factors could significantly harm any future international expansion and operations and, consequently, our business, financial condition, results of operations and prospects.

Risks Related to Ownership of our Common Stock

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

The market price of our common stock is likely to be highly volatile and may be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this section titled “Risk factors”, these factors include:

- any delay in the enrollment or ultimate completion of our existing and planned clinical trials for PIPE-791 and our existing clinical trial for PIPE-307;
- the results of our existing and planned clinical trials for PIPE-791 and our existing clinical trial for PIPE-307;
- any delay by J&J in initiating or completing clinical trials for PIPE-307, the results from any clinical trial completed by J&J for PIPE-307 or any decision by J&J not to pursue further clinical development of PIPE-307;
- the results of the clinical trials conducted by competitors developing drug candidates competitive with PIPE-791 or PIPE-307;
- our ability to develop additional drug candidates based on our clinical translational approach;
- any delay in submitting a regulatory filing for PIPE-791 or PIPE-307, and any adverse development or perceived adverse development with respect to the regulatory review of such filing;
- our failure to successfully develop and commercialize PIPE-791 and/or any future drug candidate we develop, and J&J’s failure to successfully develop and commercialize PIPE-307;
- inability to obtain additional funding to support our product development plans and operations;
- regulatory or legal developments in the United States and other countries applicable to any drug candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- adverse developments concerning our CMOs or CROs;
- inability to obtain adequate product supply to support our clinical trials, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- our ability to effectively manage our growth;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of companies similar to us;
- market conditions in the biotechnology and pharmaceutical sectors, and the issuance of new or changed securities analysts’ reports or recommendations;
- announcements of significant in-licensing transactions, acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- our inability to establish additional collaboration or licensing arrangements that we need on favorable terms, or at all;
- significant lawsuits, including patent or stockholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our drug candidates;
- additions or departures of key scientific or management personnel;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock; and
- general economic, industry and market conditions.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory, and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance.

Substantial amounts of our outstanding shares may be sold into the market when lock-up periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. After the IPO, we had 18,994,104 outstanding shares of our Class A common stock and 6,729,172 shares of our Class B common stock. All of the shares of common stock sold in the IPO are available for sale in the public market, unless purchased by our affiliates or existing stockholders. Substantially all of our outstanding shares of Class A and Class B common stock are currently restricted from resale as a result of market-standoff agreements and lock-up agreements, which restrictions may be waived by Goldman Sachs & Co. LLC and Morgan Stanley, with or without notice. The shares of common stock will become available to be sold 181 days after the date of prospectus dated April 4, 2024 filed by us with the SEC pursuant to Rule 424(b)(4) under the Securities Act; provided that shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act, and various vesting agreements. In addition, shares of common stock that are either subject to outstanding options under our 2012 Plan and/or reserved for future issuance under the 2024 Plan and/or the 2024 ESPP, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain of our stockholders have rights, subject to some conditions, to require us to file registration statements covering up to 15,906,236 of their shares or to include their shares in registration statements that we may file for ourselves or our stockholders, subject to lock-up agreements. We have registered shares of common stock that we have issued, and intend to register shares of common stock that we may issue, under our employee equity incentive plans. Once registered, they will be able to be sold freely in the public market upon issuance, subject to existing market standoff or lock-up agreements.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of Class A common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

Following our IPO, Our directors, executive officers and holders of greater than 5% of our common stock own a significant percentage of our common stock and, if they choose to act together, will be able to exert significant influence over matters subject to stockholder approval.

Following our IPO, our directors, executive officers, and holders of more than 5% of our outstanding common stock will continue to exert significant influence on us. As a result, these holders, acting together, will have significant control over all matters that require approval of our stockholders, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. In addition, participation in our IPO by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock, which could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock.

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

The dual class structure of our Class A and Class B common stock may limit your ability to influence corporate matters. Holders of our Class A common stock are entitled to one vote per share, while holders of our Class B common stock are not entitled to any votes. Nonetheless, each share of our Class B common stock may be converted at any time into one share of our Class A common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, if holders of our Class B common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our Class B common stock, and correspondingly decreasing the voting power of the holders of our Class A common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our Class A common stock and Class B common stock, but 10% or less of our Class A common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in our Class B common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

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

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard if and when we have product sales, management makes judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgements relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

We are an "emerging growth company," and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes Oxley Act");
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for private companies.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We do not intend to pay cash dividends for the foreseeable future. Consequently, you must rely on sales of our common stock after price appreciation, which may never occur, as the only way to realize any future gains on your investment.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chair of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend
- the provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. While a Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine, unless we consent in writing to the selection of an alternative forum to the extent permitted by law.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our certificate of incorporation will further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may result in stockholders incurring additional expenses in bringing a claim in the forum designated by us, which may discourage these types of lawsuits. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

General Risk Factors

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports published by securities or industry analysts about our business and the drug candidates we have developed. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business or the drug candidates we have developed, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because development stage pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

We are subject to the reporting requirements of the Exchange Act and the other rules and regulations of the SEC and Nasdaq related to public companies. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management and we will incur significant legal, accounting and other expenses that we did not incur as a private company. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that could harm our business. As a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in us, and, as a result, the value of our common stock.

To comply with the requirements of being a public company, we will need to undertake various actions, including implementing new internal controls and procedures and hiring additional accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. However, while we remain a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independently registered public accounting firm. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls when we become subject to this requirement could negatively affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on Nasdaq.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of (i) our second annual report or (ii) the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company," as defined in the JOBS Act, or a "smaller reporting company" as defined by the SEC.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. In addition, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities.

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

We have incurred substantial losses during our history, and we expect to continue to incur substantial loses in future years as we conduct clinical trials for PIPE-791 and complete the clinical trial for PIPE-307, and we may never achieve profitability. Changes in tax laws or regulations may adversely impact our ability to utilize all, or any, of our net operating loss carryforwards ("NOLs"). For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act ("TCJA") significantly revised the Internal Revenue Code of 1986, as amended (the "Code"). Future guidance from the IRS and other tax authorities with respect to the TCJA may affect us, and certain aspects of the TCJA could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") modified certain provisions of the TCJA. Under the TCJA, as modified by the CARES Act, unused losses generated in taxable years ending after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the TCJA or the CARES Act.

Under Sections 382 and 383 of the Code if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We have completed an ownership analysis and identified that ownership changes occurred in July 2012, April 2018, March 2019 and February 2021. As a result of limitations arising from the prior ownership changes, federal and California net operating loss carry-forwards and federal R&D tax credits were removed from our inventory of deferred tax assets. As of December 31, 2023, we had federal and California tax loss carry forwards of approximately $37.3 million and $81.4 million, respectively. Out of the total federal net operating losses, approximately $37.3 million were generated after December 31, 2017, and therefore do not expire. The remaining federal and state net operating loss carry forwards begin to expire in 2035 and 2036, respectively, if unused. We may experience an ownership change in connection with our IPO or in the future because of subsequent shifts in our stock ownership (some of which our outside of our control). If further requisite ownership changes occur, the amount of remaining tax attribute carryforwards available to offset taxable income and reduce income tax expense in future years may be further restricted or eliminated. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes based on restrictions in the Code, which could adversely affect our future cash flows and results of operations.

Changes in tax laws and the implementation of tax laws could adversely affect us.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the TCJA, the CARES Act, and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the IRS and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation.

We use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by the IRS or another taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations or financial condition. In addition, new legislation or regulations which could affect our tax burden could be enacted by Congress or another governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial position and results of operation.

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

(a) Recent Sales of Unregistered Securities.

None.

(b) Use of Proceeds.

On April 4, 2024, our Registration Statement on Form S-1 (333-278003) relating to the initial public offering of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we issued and sold an aggregate of 7,423,682 shares of our common stock, which includes 548,682 shares sold pursuant to the underwriters' partial exercise of their option to purchase additional shares, at the public offering price of $16.00 per share. On April 9, 2024, we closed the sale of 6,875,000 shares and on April 19, 2024, we closed the sale of the 548,682 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares. The aggregate offering price for shares sold in the IPO was approximately $118.8 million, resulting in aggregate net proceeds of approximately $108.0 million, after deducting the underwriting discounts, commissions and offering expenses paid or payable by us. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. Goldman Sachs & Co. LLC, Morgan Stanley, Stifel and RBC Capital Markets acted as joint book-running managers for the IPO.

There has been no material change in the planned use of proceeds from the IPO from those described in the final prospectus, dated April 4, 2024, filed with the SEC on April 8, 2024, pursuant to Rule 424(b) of the Securities Act.

(c) Issuer Purchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

(c) Securities Trading Plans of Directors and Executive Officers

During the quarter ended March 31, 2024, none of our officers or directors, as defined in Rule 16a-1(f), informed us of the adoption or termination of a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, each as defined in Regulation S-K Item 408.

Item 6. Exhibits

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-42001	3.1	04/09/2024	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-42001	3.2	04/09/2024	
4.1	Form of Registrant's Class A common stock certificate.	S-1/A	333-278003	4.1	04/01/2024	
4.2	Amended and Restated Investors' Rights Agreement, dated February 9, 2021, by and among the Registrant and the other parties thereto.	S-1	333-278003	4.2	03/15/2024	
4.3^	Warrant to Purchase Stock, issued to Silicon Valley Bank, dated as of September 1, 2020.	S-1	333-278003	4.3	03/15/2024	
4.4	Letter Agreement, dated as of July 9, 2021, by and among the Registrant, Baker Brothers Life Sciences, L.P. and 667, L.P.	S-1	333-278003	4.4	03/15/2024	
4.5	Amended and Restated Registration Rights Agreement dated as of July 9, 2021, by and between the Registrant and Baker Bros. Advisors LP.	S-1	333-278003	4.5	03/15/2024	
10.1+	Form of Indemnity Agreement between the Registrant and each of its directors and executive officers.	S-1/A	333-278003	10.1	04/01/2024	
10.2+	2012 Equity Incentive Plan, as amended, and forms of agreements thereunder.	S-1	333-278003	10.2	03/15/2024	
10.3+	2024 Equity Incentive Plan and form of agreements thereunder.	S-1/A	333-278003	10.3	04/01/2024	
10.4+	2024 Employee Stock Purchase Plan.	S-1/A	333-278003	10.4	04/01/2024	
10.5+	Offer Letter, dated as of August 14, 2018, by and between the Registrant and Carmine Stengone.	S-1/A	333-278003	10.5	04/01/2024	
10.6+	Offer Letter, dated as of March 9, 2018, as amended by Amendment to Original Offer Letter, dated as of December 16, 2021, each by and between the Registrant and Daniel Lorrain, Ph.D.	S-1/A	333-278003	10.6	04/01/2024	
10.7+	Offer Letter, dated as of August 20, 2020, by and between the Registrant and Peter Slover.	S-1/A	333-278003	10.7	04/01/2024	
10.8^	Lease Agreement, dated January 3, 2018, by and between ARE-SD Region No. 44, LLC and the Registrant.	S-1	333-278003	10.8	03/15/2024	
10.9	First Amendment to Lease dated February 16, 2018, by and between ARE-SD Region No. 44, LLC and the Registrant.	S-1	333-278003	10.9	03/15/2024	
10.10	Second Amendment to Lease, dated April 2, 2018, by and between ARE-SD Region No. 44, LLC and the Registrant.	S-1	333-278003	10.10	03/15/2024	
10.11	Third Amendment to Lease, dated June 15, 2021, by and between ARE-SD Region No. 44, LLC and the Registrant.	S-1	333-278003	10.11	03/15/2024	
10.12	Lease Termination, dated October 25, 2023, by and between ARE-SD Region No. 44, LLC and the Registrant.	S-1	333-278003	10.12	03/15/2024	
10.13^	Lease Agreement, dated October 25, 2023, by and between ARE-3535/3566 General Atomics Court, LLC and the Registrant.	S-1	333-278003	10.13	03/15/2024	

10.14	Loan and Security Agreement, dated as of September 1, 2020, by and between the Registrant and Silicon Valley Bank.	S-1	333-278003	10.14	03/15/2024	
10.15	First Amendment to Loan and Security Agreement, dated as of March 15, 2021, by and between the Registrant and Silicon Valley Bank.	S-1	333-278003	10.15	03/15/2024	
10.16†	License Agreement, dated February 3, 2023, by and between the Registrant and Janssen Pharmaceutica NV.	S-1	333-278003	10.16	03/15/2024	
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.					X
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.					X
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.					X
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.					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					X

+ Indicates management contract or compensatory plan.

† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions are both not material and are the type of information that the Registrant treats as private or confidential.

^ Pursuant to Item 601(a)(5) of Regulation S-K, certain exhibits and schedules have been omitted. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

* The certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates them by reference.

SIGNATURES

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

Contineum Therapeutics, Inc.

May 16, 2024

By: /s/ Carmine Stengone
Carmine Stengone
President and Chief Executive Officer
(Principal Executive Officer)

May 16, 2024

By: /s/ Peter Slover
Peter Slover
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Carmine Stengone, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

Contineum Therapeutics, Inc.

May 16, 2024

By: /s/ Carmine Stengone
Carmine Stengone
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Peter Slover, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

Contineum Therapeutics, Inc.

May 16, 2024

By: /s/ Peter Slover
Peter Slover
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Contineum Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Carmine Stengone, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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 results of operations of the Company.

Contineum Therapeutics, Inc.

May 16, 2024

By: /s/ Carmine Stengone
Carmine Stengone
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Contineum Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter Slover, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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 results of operations of the Company.

Contineum Therapeutics, Inc.

May 16, 2024

By: /s/ Peter Slover
Peter Slover
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)