UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2014

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: 001-36431

Alder BioPharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**90-0134860**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

11804 North Creek Parkway South
Bothell, WA 98011
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (425) 205-2900

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (do not check if a smaller reporting company)	Smaller reporting company	☐

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 June 13, 2014, the registrant had 30,803,668 shares of common stock, $0.0001 par value per share, outstanding.

Alder BioPharmaceuticals, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended March 31, 2014

INDEX

In this Quarterly Report on Form 10-Q, "we," "our," "us," "Alder," and "the Company" refer to Alder BioPharmaceuticals, Inc. "Alder" and the Alder logo are the property of Alder BioPharmaceuticals, Inc. This report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies

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PART I. – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Alder BioPharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

	March 31, 2014	December 31, 2013
	(in thousands, except share and per share data)	
Assets		
Current assets		
Cash and cash equivalents	$ 12,938	$ 23,227
Accounts receivable	91	316
Prepaid expenses and other assets	1,256	1,982
Total current assets	14,285	25,525
Deferred offering costs	1,316	—
Property and equipment, net	1,046	1,214
Total assets	$ 16,647	$ 26,739
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities		
Accounts payable	$ 2,135	$ 2,223
Accrued liabilities	1,962	2,128
Deferred revenue	18,579	18,717
Deferred rent	31	—
Total current liabilities	22,707	23,068
Deferred revenue	31,050	35,607
Deferred rent	84	52
Total liabilities	53,841	58,727
Commitments and contingencies		
Convertible preferred stock; $0.0001 par value; 116,020,270 shares authorized; 20,914,137 shares issued and outstanding	111,374	111,374
Stockholders' deficit		
Common stock; $0.0001 par value; 140,000,000 shares authorized; 1,013,499 and 988,685 shares issued and outstanding, respectively	—	—
Additional paid-in capital	2,625	2,443
Accumulated deficit	(151,209)	(145,814)
Accumulated other comprehensive income	16	9
Total stockholders' deficit	(148,568)	(143,362)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 16,647	$ 26,739

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

Alder BioPharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

	Three Months Ended March 31,	
	2014	2013
	(in thousands, except share and per share data)	
Revenues		
Collaboration and license agreements	$ 4,782	$ 4,599
Operating expenses		
Research and development	7,020	8,482
General and administrative	3,160	1,821
Total operating expenses	10,180	10,303
Loss from operations	(5,398)	(5,704)
Other income		
Interest income	3	22
Total other income	3	22
Net loss	$ (5,395)	$ (5,682)
Net loss per share - basic and diluted	$ (5.38)	$ (5.89)
Weighted average number of common shares used in net loss per share - basic and diluted	1,002,220	964,572

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

Alder BioPharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(unaudited)

	Three Months Ended March 31,	
	2014	2013
	(in thousands)	
Net loss	$ (5,395)	$ (5,682)
Other comprehensive income (loss):		
Foreign currency translation income (loss), net of tax	7	(3)
Total other comprehensive income (loss)	7	(3)
Comprehensive loss	$ (5,388)	$ (5,685)

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

Alder BioPharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Three Months Ended March 31,	
	2014	2013
	(in thousands)	
Operating activities		
Net loss	$ (5,395)	$ (5,682)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	188	241
Stock-based compensation	148	159
Changes in operating assets and liabilities		
Accounts receivable	225	(28)
Prepaid expenses and other assets	726	(699)
Accounts payable	(518)	40
Accrued liabilities	(296)	(578)
Deferred rent	63	(41)
Deferred revenue	(4,695)	(4,534)
Net cash used in operating activities	(9,554)	(11,122)
Investing activities		
Proceeds from maturities of investments	—	245
Purchases of property and equipment	(20)	(49)
Net cash provided by (used in) investing activities	(20)	196
Financing activities		
Deferred offering costs	(756)	—
Proceeds from exercise of stock options	34	16
Net cash provided by (used in) financing activities	(722)	16
Effect of exchange rate changes on cash	7	(3)
Net decrease in cash and cash equivalents	(10,289)	(10,913)
Cash and cash equivalents		
Beginning of period	23,227	53,753
End of period	$ 12,938	$ 42,840
Supplemental disclosures:		
Increase in deferred offering costs included in accounts payable and accrued liabilities	$ 560	$ —

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

1. Nature of Business

Alder BioPharmaceuticals, Inc. (the "Company") is a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize therapeutic antibodies with the potential to transform current treatment paradigms. The Company uses its proprietary antibody platform designed to select and manufacture antibodies that have the potential to maximize efficacy as well as speed of onset and durability of therapeutic response. Through collaboration and licensing agreements, the Company has used its proprietary technology to help a major biopharmaceutical partner advance a novel therapeutic antibody to the clinic. The Company was incorporated in Delaware on May 20, 2002 and is located in Bothell, Washington.

Reverse Stock Split

On April 9, 2014, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation to effect a 1-for-5.5 reverse stock split of its outstanding common stock and convertible preferred stock. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split. All issued and outstanding shares of common stock and preferred stock, options to purchase common stock and related per share amounts contained in the condensed consolidated financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Initial Public Offering

In May 2014, the Company completed an initial public offering ("IPO") of its common stock. In connection with its IPO, the Company issued and sold 8,875,396 shares of its common stock, which included 875,396 shares the Company issued pursuant to the underwriters' partial exercise of their over-allotment option, at a price to the public of $10.00 per share. The Company's shares of common stock began trading on the NASDAQ Global Market on May 8, 2014. As a result of the IPO, the Company received approximately $80.1 million in net proceeds, after deducting underwriting discounts and commissions of $6.2 million and estimated offering expenses of $2.4 million payable by the Company. At the closing of the IPO, 20,914,137 shares of outstanding convertible preferred stock were automatically converted into 20,914,137 shares of common stock. Following the IPO, there were no shares of preferred stock outstanding. In connection with the IPO, the Company amended and restated its Amended and Restated Certificate of Incorporation to change the authorized capital stock to 200,000,000 shares designated as common stock and 10,000,000 shares designated as preferred stock, all with a par value of $0.0001 per share. As of March 31, 2014, the Company had incurred $1.3 million of deferred offering costs, which will be offset against the net proceeds received from the sale of common stock. The condensed consolidated financial statements, including share and per share amounts, do not give effect to the IPO.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of Alder BioPharmaceuticals, Inc. and its wholly-owned subsidiaries. All inter-company balances and transactions have been eliminated in consolidation. The condensed consolidated balance sheet data as of December 31, 2013 were derived from audited financial statements. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and generally accepted accounting principles in the United States of America ("GAAP") for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. The Company manages its business as one operating segment; however, the Company operates in two geographic regions: United States (Bothell, WA) and Australia. Substantially all of the Company's assets are located in, and revenues are generated in, the United States.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the prospectus that forms a part of the Company's Registration Statement on Form S-1 (File No. 333-194672), which prospectus was filed with the SEC pursuant to Rule 424 promulgated under the Securities Act of 1933 on May 8, 2014.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The results of the Company's operations for the three month period ended March 31, 2014 are not necessarily indicative of the results to be expected for the full year or for any other period.

Concentrations of Credit Risk and Major Collaborators

The Company is exposed to credit risk from its deposits of cash and cash equivalents and restricted cash in excess of amounts insured by the Federal Deposit Insurance Corporation.

One of the Company's collaborators accounted for nearly 100% of total revenues for the three months ended March 31, 2014 and 2013. This collaborator accounted for nearly 100% of total accounts receivable as of March 31, 2014 and December 31, 2013.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update 2013-11 Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists that provides for disclosure requirements related to unrecognized tax benefits in certain situations. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09 Revenue from Contracts with Customers that creates modifications to various other revenue accounting standards for specialized transactions and industries. The section is intended to conform revenue accounting principles with a concurrently issued International Financial Reporting Standards with previously differing treatment between United States practice and those of much of the rest of the world, as well as, to enhance disclosures related to disaggregated revenue information. The updated guidance is effective for annual reporting periods beginning on or after December 15, 2016, and interim periods within those annual periods. Early adoption is not permitted. The Company will further study the implications of this statement in order to evaluate the expected impact on the consolidated financial statements.

The Company has reviewed other recent accounting pronouncements and concluded that they are either not applicable to the business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

As an "emerging growth company," the Jumpstart our Business Startups Act, or the JOBS Act, allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. As a result, the Company's financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective date for new or revised accounting standards that are applicable to public companies.

3. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted average common shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method.

	March 31,	
	2014	2013
Net loss (in thousands)	$ (5,395)	$ (5,682)
Weighted-average common shares outstanding -basic and diluted	1,002,220	964,572
Net loss per share-basic and diluted	$ (5.38)	$ (5.89)

The following convertible preferred stock and outstanding stock options were excluded from the calculation of diluted net loss per share for periods ended as of the dates indicated because including them would have had an anti-dilutive effect. Therefore, basic and diluted net loss per share were the same for all periods presented. The convertible preferred stock numbers shown in the table are on a common stock equivalent basis.

	March 31,	
	2014	2013
Conversion of Series A preferred stock	3,770,267	3,770,267
Conversion of Series B preferred stock	4,556,638	4,556,638
Conversion of Series C preferred stock	6,767,673	6,767,673
Conversion of Series D preferred stock	5,819,559	5,819,559
Stock options	2,214,157	2,218,103
	23,128,294	23,132,240

4. Fair Value Disclosures

The Company holds financial instruments that are measured at fair value which is determined according to a fair value hierarchy that prioritizes the inputs and assumptions used, and the valuation techniques used to measure fair value. The three levels of the fair value hierarchy are described as follows:

Level 1 Inputs are unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs are quoted prices for similar assets and liabilities in active markets or quoted prices for identical or similar instruments in markets that are not active and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Inputs are unobservable inputs based on the Company's own assumptions and valuation techniques used to measure assets and liabilities at fair value. The inputs require significant management judgment or estimation.

The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

The Company established the fair value of its assets and liabilities using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and established a fair value hierarchy based on the inputs used to measure fair value.

The following table presents the Company's financial instruments by level within the fair value hierarchy:

	Fair Value Measurement Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
As of December 31, 2013				
Cash equivalents				
Money market funds	$ 22,238	$ —	$ —	$ 22,238
As of March 31, 2014				
Cash equivalents				
Money market funds	$ 11,940	$ —	$ —	$ 11,940

Accounts receivable, accounts payable and accrued liabilities are carried at cost, which approximates fair value due to the short-term nature of these financial instruments.

5. Deferred Offering Costs

Deferred offering costs represent legal, accounting and other direct costs related to the Company's efforts to raise capital through an IPO of the Company's common stock. These costs have been deferred through the completion of the IPO and were reclassified to additional paid-in capital as a reduction of the proceeds. The Company recorded $1.3 million of deferred offering costs as a non-current asset in the accompanying balance sheets as of March 31, 2014.

6. Subsequent Events

Initial Public Offering

In May 2014, the Company completed its IPO of 8,875,396 shares of common stock, which included 875,396 shares of common stock the Company issued pursuant to the underwriters' exercise of their over-allotment option, at a price to the public of $10.00 per share. See Note 1 – Nature of Business – Initial Public Offering for additional information regarding the IPO.

Equity Compensation Plans

In April 2014, the Company's stockholders approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective in May 2014 at which time the 2005 Stock Option Plan (the "2005 Plan") was terminated. The 2014 Plan provides for the grant of stock options, other forms of equity compensation, and performance cash awards. The maximum number of shares of common stock that may be issued under the 2014 Plan is 3,963,757. The actual number of shares that may be issued under the 2014 Plan includes 1,535,000 new shares, plus 211,881, which was the number of shares of common stock remaining available for issuance under the 2005 Plan and 2,213,522 which was the maximum number of shares of common stock subject to outstanding awards under the 2005 Plan when the 2014 Plan became effective, that could expire or terminate for any reason prior to exercise or settlement. In addition, the number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015 and ending on and including January 1, 2024, by 4% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors.

In April 2014, the Company's stockholders approved the 2014 Employee Stock Purchase Plan (the "ESPP") which became effective in May 2014. The initial number of shares of common stock that may be issued under the ESPP is 274,000 shares and the number of shares reserved for the ESPP will increase automatically each year, beginning on January 1, 2015 and continuing through and including January 1, 2024, by the lesser of (1) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year; (2) 750,000 shares of common stock; or (3) such lesser number as determined by the Company's board of directors.

Reverse Stock Split

On April 9, 2014, the Company effected a 1-for-5.5 reverse stock split of its outstanding common stock and convertible preferred stock. See Note 1 – Nature of Business – Reverse Stock Split for additional information regarding the reverse stock split.

Item 2. **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This section should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2013 included in our prospectus dated May 7, 2014, filed with the Securities and Exchange Commission, or SEC, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, or the Securities Act, on May 8, 2014.

Forward-Looking Statements

This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors," and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments..

Overview

We are a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize therapeutic antibodies with the potential to meaningfully transform current treatment paradigms. We have developed a proprietary antibody platform designed to select antibodies that have the potential to maximize efficacy as well as speed of onset and durability of therapeutic response. In addition, we believe our ability to efficiently manufacture antibodies using our yeast-based manufacturing technology, MabXpress, allows us to target diseases that traditionally have not been addressed by antibodies. Both our lead product candidates were discovered internally, have achieved proof-of-concept and are expected to enter final Phase 2b dose-ranging trials in 2014 in preparation for progression to Phase 3 trials if supported by the data.

ALD403 is our wholly-owned novel monoclonal antibody targeted to calcitonin gene-related peptide, or CGRP, for migraine prevention. We recently completed a three month randomized, placebo-controlled proof-of-concept trial of ALD403 in 163 patients suffering from five to 14 migraine days per month, or high frequency migraine. We plan to initiate a Phase 2b dose-ranging trial in the second half of 2014, with the goal of initiating pivotal Phase 3 trials in 2016.

Clazakizumab is a novel monoclonal antibody that inhibits the pro-inflammatory cytokine interleukin-6, or IL-6, and is being developed for both rheumatoid arthritis, or RA, and psoriatic arthritis, or PsA. In November 2009, we entered into a license and collaboration agreement with Bristol-Myers Squibb, or BMS, for the development and commercialization of Clazakizumab and received an $85 million upfront payment. BMS is responsible for paying 100% of worldwide development costs for all indications, except cancer, and reimbursing us for certain clinical supply and development costs, subject to us being responsible for approximately 50% of costs incurred by us for development of manufacturing process improvements up to certain caps with respect to such costs. To date, in addition to the upfront payment, we have received two milestone payments totaling $18.5 million in the aggregate and reimbursed clinical supply and development costs of $26.7 million. We may also receive additional development-based and regulatory-based milestone payments of up to $394.0 million in RA. In addition, if Clazakizumab is commercialized for RA, we may receive sales-based milestones up to $500.0 million and tiered royalties starting in the mid-teens up to 20% on net sales of Clazakizumab. Under the collaboration agreement, we are entitled to additional milestone payments and royalties for additional indications, subject to certain reductions.

We are currently evaluating four programs with the view of advancing at least one candidate into the clinic in 2015 for a disease indication where therapeutic antibodies have not previously played a role. We will continue to enhance our technologies to discover optimized product candidates that can be manufactured efficiently on a very large scale. We may seek to monetize our technology platform by consummating partnerships with leading biotechnology and pharmaceutical companies. We also intend to continue to deploy capital to selectively develop our own portfolio of product candidates.

As of March 31, 2014, we had an accumulated deficit of $151.2 million. We expect to experience increasing operating losses for the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- conduct clinical trials for ALD403;
- continue to evaluate our preclinical programs and advance at least one product candidate into the clinic;
- enhance our proprietary antibody platform and conduct discovery and preclinical activities;
- manufacture antibodies for our preclinical programs and clinical trials;
- seek regulatory approval for our product candidates; and
- operate as a public company.

We will not generate revenues from product sales unless and until we or our collaborators successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for ALD403 or any future product candidate, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such costs are not paid by future collaborators. Our ability to generate product revenues and become profitable may also depend upon BMS's ability to successfully commercialize Clazakizumab.

Recent Developments

In May 2014, we completed our initial public offering, or IPO of 8,875,396 shares of common stock, which included 875,396 shares of common stock we issued pursuant to the underwriters' partial exercise of their over-allotment option, at an initial public offering price of $10.00 per share. The proceeds from the IPO were $80.1 million net of underwriting discounts and commissions and offering expenses.

Financial Operations Overview

Revenues

Substantially all of our revenues in the three months ended March 31, 2014 and 2013 were derived from our collaboration with BMS. Upfront fees, milestone payments and reimbursed clinical supply and development costs received under our collaboration agreements are deferred and are recognized as revenues over the development period using a time-based approach. Revenues recognized and cash payments received under these agreements were as follows:

	Three Months Ended March 31,	
	2014	2013
	(in thousands)	
Revenues recognized:		
Bristol-Myers Squibb:		
Amortization of deferred revenue from upfront payments	$ 2,992	$ 2,992
Recognition of milestone payments	651	651
Recognition of reimbursed clinical supply and development costs	989	956
Bristol-Myers Squibb total	4,632	4,599
Other collaborations	150	—
Total revenues recognized	$ 4,782	$ 4,599
Cash payments received:		
Bristol-Myers Squibb:		
Reimbursed clinical supply and development costs	$ 62	$ 38
Bristol-Myers Squibb total	62	38
Other collaborations	250	—
Total cash payments received	$ 312	$ 38

We have not generated any revenues from the sale of products. In the future, we may generate revenues from product sales and from collaboration agreements in the form of license fees, milestone payments, reimbursements for clinical supply and development costs and royalties on product sales. We expect that any revenues we generate will fluctuate from quarter to quarter as a result of the uncertain timing and amount of such payments and sales.

Research and Development Expenses

Research and development expenses represent costs incurred by us for the discovery and development of our product candidates. The following items are included in research and development expenses:

- external costs under agreements with clinical research organizations, or CROs, contract manufacturing organizations, or CMOs, and other significant third-party vendors or consultants used to perform preclinical, clinical and manufacturing activities;
- internal costs including employee-related costs such as salaries, benefits, stock-based compensation expense, travel, laboratory consumables and services for our research and development personnel; and
- allocated facilities, depreciation, and other expenses, which include rent and maintenance of facilities, information technology services and other infrastructure expenses.

We use our employee and infrastructure resources across multiple research and development programs directed toward evaluating our monoclonal antibodies for selecting product candidates. We manage certain activities such as preclinical toxicology studies, clinical trial operations and manufacture of product candidates through third-party CROs, CMOs or other third-party vendors. We track our significant external costs by each product candidate. We also track our human resource efforts on certain programs for purposes of billing our collaborators for time incurred at agreed upon rates. We do not, however, assign or allocate to individual product candidates or development programs our internal costs and we group these internal research and development activities into three categories:

Category	Description
Preclinical discovery and development	Research and development expenses incurred in activities substantially in support of discovery of new targets through the selection of a single product candidate. These activities encompass the discovery and translational medicine functions, including pharmacokinetic and drug metabolism preclinical studies, toxicology and early strain and assay development activities.
Pharmaceutical operations	Research and development expenses incurred related to manufacturing preclinical study and clinical trial materials, including scale-up process development and quality control activities.
Clinical development	Research and development expenses incurred related to Phase 1, Phase 2 and Phase 3 clinical trials, including regulatory affairs activities.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of ALD403 and the evaluation and advancement of future product candidates into clinical development. The timing and amount of research and development expenses incurred will depend largely upon the outcomes of current and future clinical trials for our product candidates as well as the related regulatory requirements, manufacturing costs and any costs associated with the advancement of our preclinical programs. We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results;
- potential changes in government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, business development, intellectual property, finance, human resources and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses and professional fees for auditing, tax and legal services, including intellectual property related legal services. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services.

Results of Operations

Comparison of the Three Months Ended March 31, 2014 and 2013

The following table summarizes our results of operations for the three months ended March 31, 2014 and 2013, together with the changes in those items in dollars and as a percentage:

	Three Months Ended March 31,			
	2014	2013	Dollar change	% change
	(dollars in thousands)			
Revenues:				
Collaboration and license agreements	$ 4,782	$ 4,599	$ 183	4%
Operating expenses:				
Research and development	7,020	8,482	(1,462)	(17%)
General and administrative	3,160	1,821	1,339	74%
Loss from operations	(5,398)	(5,704)	306	(5%)
Interest income	3	22	(19)	(86%)
Net loss	$ (5,395)	$ (5,682)	$ 287	(5%)

Revenues

Revenues for the three months ended March 31, 2014 and 2013 were derived primarily from our collaboration agreement with BMS. Revenues increased by $0.2 million, or 4%, for the three months ended March 31, 2014 compared to the same period of 2013 due to revenue recognized from other collaborations.

Research and Development Expenses

	Three Months Ended March 31,			
	2014	2013	Dollar change	% change
	(dollars in thousands)			
External costs:				
ALD403	$ 2,108	$ 2,364	$ (256)	(11%)
Clazakizumab	467	1,150	(683)	(59%)
Unallocated internal costs:				
Preclinical discovery and development	2,887	3,075	(188)	(6%)
Pharmaceutical operations	1,184	1,293	(109)	(8%)
Clinical development	374	600	(226)	(38%)
Total research and development expenses	$ 7,020	$ 8,482	$ (1,462)	(17%)

Research and development expenses decreased $1.5 million, or 17%, for the three months ended March 31, 2014 compared to the same period of 2013. External costs for ALD403 decreased $0.3 million due to the timing of costs relating to the proof-of-concept clinical trial during 2013. External costs for Clazakizumab decreased by $0.7 million due to the timing of costs incurred for our clinical trial in cancer. In 2013 we decided to discontinue the development of Clazakizumab in cancer. We anticipate incurring expenses of $1.7 million during the remainder of 2014 as our clinical trial in cancer concludes.

Unallocated internal costs decreased $0.5 million for the three months ended March 31, 2014 compared to the same period of 2013. The decrease was primarily attributable to decreased activities related to our preclinical programs of $0.3 million and a decrease in personnel-related costs of $0.2 million.

General and Administrative Expenses

General and administrative expenses increased by $1.3 million, or 74%, for the three months ended March 31, 2014 compared to the same period of 2013 due to an increase in professional fees of $0.7 million related primarily to legal fees for our patent filings, an increase of $0.5 million in other professional fees, and an increase in personnel-related expenses of $0.1 million.

Interest Income

The decrease of $19,000 in interest income is primarily due to a decrease in average cash, cash equivalents and short-term investments during the three months ended March 31, 2014 compared to the same period of 2013.

Liquidity and Capital Resources

Due to our significant research and development expenditures, we have generated significant operating losses since our inception. We have funded our operations primarily through sales of our convertible preferred stock, payments from our collaboration partners and our IPO. As of March 31, 2014, we had available cash and cash equivalents of $12.9 million, which consisted of cash and money market accounts. We received $80.1 million of proceeds, net of underwriting discounts and commissions and offering expenses, from our IPO. We completed our IPO in May 2014, and accordingly, such proceeds are not reflected in our cash and cash equivalents at March 31, 2014.

We believe that our available cash and cash equivalents and including the net proceeds of our IPO will be sufficient to meet our projected operating requirements through at least 2015. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Furthermore, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital other than potential milestones receivable under our collaboration agreement with BMS. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, as we:

- initiate or continue clinical trials of ALD403, our wholly-owned novel monoclonal antibody for prevention of migraine;
- continue the research and development of our product candidates;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize products which receive regulatory approval;
- enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercialization efforts; and
- incur additional costs associated with becoming a public company.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. We may also consider new collaborations or selectively partnering ALD403 for further clinical development and commercialization outside of the United States. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are not able to secure adequate additional funding we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could harm our business, results of operations and future prospects.

Historical Cash Flow Trends

The following table summarizes our cash flows for the periods indicated:

	Three Months Ended March 31,	
	2014	2013
Net cash used in operating activities	$ (9,554)	$ (11,122)
Net cash provided by (used in) investing activities	(20)	196
Net cash provided by (used in) financing activities	(722)	16

Cash Used in Operating Activities

Net cash used in operating activities in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was $9.6 million during the three months ended March 31, 2014 compared to $11.1 million during the same period of 2013. The decrease in cash used in operating activities in the three months ended March 31, 2014 compared to the same period of 2013 was driven primarily by a decrease in net loss of $0.3 million and changes in prepaid expenses and other assets.

Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $20,000 in the three months ended March 31, 2014 due to purchases of property and equipment. Net cash provided by investing activities was $0.2 million in the three months ended March 31, 2013 due primarily to the maturity of investments, offset in part by purchases of property and equipment.

Cash Provided by (Used in) Financing Activities

Cash used in financing activities in the three months ended March 31, 2014 included $0.8 million of payments for deferred offering costs offset in part by proceeds from stock option exercises. In the three months ended March 31, 2013, cash provided by financing activities was the result of stock option exercises.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements in the three months ended March 31, 2014.

Contractual Obligations

Our future minimum contractual commitments as of December 31, 2013 were reported in our prospectus dated May 7, 2014 filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, or Securities Act. There have been no other material changes from the contractual commitments previously disclosed in that prospectus.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no significant and material changes in our critical accounting policies during the three months ended March 31, 2014, as compared to those disclosed in "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS - Critical Accounting Policies and Significant Judgments and Estimates" in our prospectus dated May 7, 2014 filed with the SEC pursuant to Rule 424(b) under the Securities Act. We believe that the accounting policies discussed in such prospectus are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Newly Adopted Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update 2013-11 *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* that provides for disclosure requirements related to unrecognized tax benefits in certain situations. We adopted this standard in the first quarter of 2014 which did not have a material impact on our consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09 *Revenue from Contracts with Customers* that creates modifications to various other revenue accounting standards for specialized transactions and industries. The section is intended to conform revenue accounting principles with a concurrently issued International Financial Reporting Standards with previously differing treatment between United States practice and those of much of the rest of the world, as well as, to enhance disclosures related to disaggregated revenue information. The updated guidance is effective for annual reporting periods beginning on or after December 15, 2016, and interim periods within those annual periods. Early adoption is not permitted. We will further study the implications of this statement in order to evaluate the expected impact on the consolidated financial statements.

JOBS Act

As an "emerging growth company," the Jumpstart our Business Startups Act, or the JOBS Act, allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective date for new or revised accounting standards that are applicable to public companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Management believes there have been no material changes to our quantitative and qualitative disclosures about market risks during the three months ended March 31, 2014, compared to those discussed in our prospectus dated May 7, 2014 filed with the SEC pursuant to Rule 424(b) under the Securities Act.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Our management, with the participation of our Chief Executive Officer and our Senior Vice President, Finance, our principal financial officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our Chief Executive Officer and our Senior Vice President, Finance, have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were, in design and operation, effective.

Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting during the quarter ended March 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II. – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report on Form 10-Q 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 factors that are described below and elsewhere in this report.

Risks Related to Our Business and the Development and Commercialization of Our Product Candidates

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

We are a clinical-stage biopharmaceutical company. We do not currently have any products approved for sale, and we continue to incur significant research and development and general and administrative expenses. We have incurred significant operating losses in the past and expect to incur substantial and increasing losses for the foreseeable future. Our net loss was $17.8 million, $20.6 million and $5.3 million for 2012, 2013, and the three months ended March 31, 2014, respectively. As of March 31, 2014, we had an accumulated deficit of $151.2 million.

To date, we have devoted substantially all of our efforts to research and development, including clinical trials, but have not completed development or commercialized any product candidates. We anticipate that our expenses will increase substantially as we:

- continue the research and development of our product candidates, including clinical trials of ALD403;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize ALD403 if it receives regulatory approval; and
- enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercialization efforts.

To be profitable in the future, we and our collaborators must succeed in developing and eventually commercializing products with significant market potential. This will require success in a range of activities, including advancing product candidates, completing clinical trials of product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which regulatory approval is obtained. We are only in the preliminary stages of some of these activities. We and our collaborators may not succeed in these activities and may never generate revenues that are sufficient to be profitable in the future.

Drug development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenues from product sales and may never be profitable.

We have devoted substantially all of our financial resources and efforts to developing our technology platform, identifying product candidates and conducting preclinical studies and clinical trials for our product candidates. We are still in the early stages of developing our product candidates and have not completed the development of any products. We have never generated revenues from the sale of any products. Our ability to generate revenues and achieve profitability depends in large part on our ability, on our own or with our collaborators, to achieve milestones and to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our product candidates. We do not anticipate generating revenues from sales of products for the foreseeable future. Our ability to generate future revenues from product sales depends on our and our collaborators' success in:

- completing clinical development and obtaining regulatory approval for ALD403 and Clazakizumab;
- achieving the milestones set forth in our collaboration agreement with Bristol-Myers Squibb, or BMS, and any future collaboration agreements;
- launching and commercializing ALD403, if approved, and successfully establishing sales, marketing and distribution infrastructure;
- obtaining regulatory approvals for future product candidates that we discover and successfully develop;
- establishing and maintaining supply and manufacturing relationships with third parties; and
- maintaining, protecting, expanding and enforcing our intellectual property, including intellectual property we license from third parties.

Because of the numerous risks and uncertainties associated with biologic product development, we are unable to predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. In addition, our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, or foreign regulatory agencies, to perform studies and trials in addition to those that we currently anticipate, or if there are any delays in our or our collaborators' clinical trials or the development of any of our product candidates. If one or more of the product candidates that we independently develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing such product candidates.

We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts.

We are focused on the advancement of ALD403 through the clinical development process, as well as the evaluation of future product candidates. The completion of the development and the potential commercialization of our product candidates, should they receive regulatory approval, will require substantial funds. As of March 31, 2014, we had $12.9 million in cash and cash equivalents. We believe that our available cash and cash equivalents and net proceeds from our IPO will be sufficient to fund our anticipated level of operations through at least 2015. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the achievement of milestones and receipt of payments under our collaboration agreement with BMS for Clazakizumab;
- the rate of progress, recruitment and cost of our clinical trials and clinical success for ALD403 and any future product candidates;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the costs of commercialization activities if any of our product candidates, such as ALD403, receive regulatory approval, including sales, marketing and distribution infrastructure;
- the degree and rate of market acceptance of any products launched by us, BMS or future collaborators;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

We do not have any material committed external source of funds or other support for our development efforts other than our collaboration agreement with BMS for the development and commercialization of Clazakizumab, which agreement is terminable by BMS without cause upon four months' notice. If BMS terminates our collaboration agreement, or delays development of Clazakizumab, we would need to obtain substantial additional sources of funding to develop ALD403 as currently contemplated. If such additional funding is not available on favorable terms or at all, we may need to delay or reduce the scope of our ALD403 development program or grant rights in the United States, as well as outside the United States, to ALD403 to one or more partners.

Until we can generate sufficient revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, buying or selling assets, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, suspend or eliminate one or more of our clinical trials or research and development programs or our commercialization efforts.

In addition, our planned clinical trial for ALD403 may encounter manufacturing, enrollment or other issues that could cause our development costs to increase more than we expect. Even with the net proceeds from our IPO, we do not have sufficient cash to complete the clinical development of any of our product candidates and will require additional funding in order to complete the development activities required for regulatory approval of ALD403 or any future product candidates that we develop independently. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our product candidates.

Furthermore, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

If Clazakizumab or ALD403 is not successfully commercialized, our business will be harmed.

We currently only have two product candidates in clinical trials. We have entered into a collaboration agreement with BMS for the commercialization and development of Clazakizumab. Pursuant to our agreement, BMS makes all the final decisions regarding development and commercialization of Clazakizumab in all diseases other than cancer, which we retained, subject to BMS's option to co-develop Clazakizumab for cancer and commercialize Clazakizumab for cancer outside the United States. We also have invested a significant portion of our efforts and financial resources into the development of ALD403 to prevent migraines. Our ability to generate revenues from products, which we do not expect to occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of our product candidates. The success of these product candidates will depend on several factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- our ability, with respect to ALD403, or BMS's ability, with respect to Clazakizumab, to reach agreements with the FDA and other regulatory authorities on the appropriate regulatory path for approval for these product candidates;
- receipt of approvals from the FDA and similar regulatory authorities outside the United States for these product candidates;
- establishing commercial manufacturing arrangements with third parties;
- successfully launching sales, marketing and distribution of any product candidate that may be approved, whether alone or in collaboration with others;
- acceptance of any approved product by the medical community, third-party payors and patients and others involved in the reimbursement process, such as the National Institute of Clinical Excellence in the United Kingdom;
- effectively competing with other therapies;
- achieving a continued acceptable safety profile of the product following approval, including intellectual property we license from third parties; and
- obtaining, maintaining, enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we or our collaborators must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of such clinical trials could occur at any stage of evaluation. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

In some cases, we utilize novel mechanisms of action to treat diseases that have not previously been addressed by antibody therapies. We or our collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our or our collaborators' ability to receive regulatory approval or commercialize our product candidates, including the following:

- clinical trials of our product candidates may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we or our collaborators anticipate, enrollment in these clinical trials may be insufficient or slower than anticipated or patients may drop out of these clinical trials at a higher rate than anticipated;
- the cost of clinical trials of our product candidates may be greater than anticipated;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us or our collaborators in a timely manner, or at all;
- we or our collaborators might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that our product candidates have unanticipated serious side-effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve our or our collaborators' proposed clinical development plans;
- regulators or institutional review boards may not authorize us, our collaborators or our investigators to commence a clinical trial or conduct a clinical trial at a prospective site;
- regulators or institutional review boards may require that we, our collaborators or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we or our collaborators are required to conduct additional clinical trials or other testing of our product candidates beyond those currently contemplated, if we or our collaborators are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our collaborators may:

- be delayed in obtaining regulatory approval for our product candidates;
- not obtain regulatory approval at all;
- obtain regulatory approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

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

The results of clinical trials conducted at sites outside the United States may not be accepted by the FDA and the results or clinical trials conducted at sites inside the United States may not be accepted by international regulatory authorities.

We have conducted, and may in the future choose to conduct, one or more of our clinical trials outside the United States. In addition, BMS is currently conducting a Phase 2b trial of Clazakizumab in U.S. and international sites. Regions that are planned for inclusion in this trial include Australia, Argentina, Europe, Japan, Mexico and South Africa. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our or BMS's international clinical trials, or if international regulatory authorities do not accept the data from our or BMS's U.S. clinical trials, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt the development of a product candidate.

The development and commercialization of biologic products is subject to extensive regulation, and we may not obtain regulatory approvals for any of our product candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to ALD403, Clazakizumab and any other product candidate that we may develop in the future are subject to extensive regulation in the United States. Biologics, like ALD403 and Clazakizumab, require the submission of a Biologics License Application, or BLA, to the FDA and such product candidates are not permitted to be marketed in the United States until approval from the FDA of a BLA for that product has been obtained. A BLA must be supported by extensive preclinical and clinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, sufficient to demonstrate the safety, purity, potency and effectiveness of the applicable product candidate to the satisfaction of the FDA. We have not submitted an application for approval or obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for ALD403 and our future product candidates.

Regulatory approval of a BLA is not guaranteed, and the approval process is an expensive and uncertain process that may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that require us to repeat or perform additional preclinical studies or clinical trials or generate additional CMC data. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem the product candidate to be adequately safe or effective;
- may not find the data from preclinical studies, clinical trials or CMC data to be sufficient to support a claim of safety and efficacy;
- may not approve the manufacturing processes or facilities associated with the product candidate;
- may conclude that the long-term stability of the formulation of the drug product for which approval is being sought has been sufficiently demonstrated;
- may change approval policies or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

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

We face substantial competition, and others may discover, develop or commercialize products before or more successfully than we do.

The development and commercialization of new therapeutic products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products, which are expected to become available over the coming years. For example, if approved, we expect that by the time Clazakizumab enters the marketplace, there may be several anti-TNF biosimilars on the marketplace. The entry of such products could potentially put pricing pressure on Clazakizumab. In addition, many of our competitors are large pharmaceutical companies that have a greater ability to reduce prices for their competing drugs in an effort to maintain or gain market share and undermine the value proposition that drugs commercialized by us might otherwise be able to offer to payors.

Potential competitors also include academic institutions, government agencies and other public and private organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

BMS is currently developing Clazakizumab for the treatment of the autoimmune disorders rheumatoid arthritis, or RA, and psoriatic arthritis, or PsA. Several large pharmaceutical and biotechnology companies currently market and sell biologics for the treatment of RA, including BMS's Orencia. The current standard of care for the treatment of RA after the immunosuppressive drug methotrexate, or MTX, is biologic therapy. Currently the market for biologic therapy is dominated by anti-TNFs, primarily Humira and Enbrel. In addition, there are several other agents currently in development, including monoclonal antibody therapies that modulate IL-6-biology and other oral medications. As a result, BMS may face difficulties in marketing Clazakizumab in this competitive market.

Currently in the United States, there are relatively few medications approved for the prevention of high frequency migraines. Most of the medications used today are generics that are prescribed for abortive treatment of migraines. Botox is approved for the prevention of chronic migraine but is also prescribed for high frequency migraine. There are also several other companies, including Amgen, Lilly and Labrys, that have ongoing clinical trials for CGRP blocking therapies using monoclonal antibodies similar to ALD403. Other companies may be in later stages of development than we are or may progress their product candidates through clinical trials faster than our product candidates and, therefore, may obtain FDA or other regulatory approval for their products before we obtain approval for ours. For example, we are aware that Amgen has initiated its Phase 2b clinical trial and may be able to initiate Phase 3 clinical trials as early as 2015.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, 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. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. It is possible that our competitors might get FDA or other regulatory approval for their products before us. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Delays in the enrollment of patients in our clinical trials could increase our development costs and delay completion of the trials and delays in enrollment of patients in our collaborators' clinical trials could delay completion of our collaborators' trials.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

For example, our planned Phase 2b clinical trial for ALD403 is expected to enroll approximately 750 patients at more than 40 sites throughout the world. We have never previously conducted a trial of this magnitude and can provide no assurance that we will be able to enroll patients at a sufficient pace to complete the clinical trial within our projected time frame. Completing future migraine trials will require us to continue to activate new clinical trial sites and to enroll patients at forecasted rates at both new and existing clinical trial sites. Our forecasts regarding the rates of clinical site activation and patient enrollment at those sites are based on a number of assumptions, including assumptions based on experience with our last ALD403 clinical trial. However, there can be no assurance that those forecasts will be accurate or that we will complete, following collection of six month data, our next ALD403 trial on schedule. We anticipate completion in the first half of 2015. During the initial months of this planned clinical trial, the number of clinical sites activated and the number of patients enrolled at each clinical site per month could be lower than we have forecasted and, as a result, we might need to make a number of adjustments to the clinical trial plan, including increasing the number of clinical trial sites. We can provide no assurance that those adjustments will be sufficient to enable us to complete the study within our anticipated time frame. If we experience delays in enrollment, our ability to complete the study could be materially adversely affected.

We expect BMS will need to enroll approximately 140 patients in the Phase 2b, dose-ranging clinical trial for Clazakizumab in RA. This Phase 2b trial targets enrollment of patients who have had an inadequate response to anti-TNF therapies. This patient population can be challenging to enroll due to the cycling of patients through multiple anti-TNF therapies before concluding the patients are inadequate responders. There can be no assurance that BMS' forecasted patient enrollment rate for this trial will be accurate. For example, BMS recently updated its patient enrollment forecast and expects an additional three months will likely be needed to complete enrollment in the Phase 2b trial so we now expect that the Phase 2b trial will be completed three months later in the first half of 2015 rather than at the end of 2014, as previously expected. Completion of this Phase 2b trial could be further delayed if the measures instituted by BMS to enhance the patient enrollment rate in such trial are not successful. In addition, BMS will need to recruit over 1,000 patients at numerous sites throughout the world to complete the multiple Phase 3 trials that would be required by the FDA for approval of Clazakizumab in RA. There can be no assurance that BMS will commit the resources required to activate the number of trial sites, and enroll the number of patients, required to complete these clinical trials in a timely manner or at all. Even if BMS commits significant resources to activating sites and enrolling RA patients, the pace of enrollment could be adversely affected by competition with other trials enrolling RA patients. A slower pace of enrollment could increase the development costs for Clazakizumab which could adversely affect BMS's commitment to developing Clazakizumab in RA, or at all.

If serious adverse side-effects are identified during the development of any of our product candidates, we or our collaborators may need to abandon development of that product candidate.

Our lead product candidates are still in clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective and safe enough to receive regulatory approval. To date, the safety profile observed in the Clazakizumab trials have been consistent with other previously approved anti-IL-6 inhibitors. The most frequent serious adverse events, or SAEs, for Clazakizumab were serious infections. Additionally, patients in clinical trials for Clazakizumab exhibited increases in mean total cholesterol without changes in HDL/LDL ratio, increases in hemoglobin, increases in liver function tests and decreases in neutrophils, a type of white blood cell, and platelets, which are expected from IL-6 inhibition.

With respect to ALD403, while we have observed few SAEs to date, ALD403 has only been evaluated in a limited number of patients. The observed SAEs to date include inguinal hernia, kidney infection, transient ischemic attack, which is a precursor to stroke, conversion disorder, which is a mental health condition in which a person has blindness, paralysis, or other nervous system symptoms that cannot be explained by medical evaluation, chest pain, shortness of breath and wound infection. Each of these events was observed a single time in the ALD403 trial, with no one patient exhibiting more than one SAE. The clinical investigator concluded that all of these events were found to be unrelated to ALD403.

There can be no assurance that our planned trials for ALD403 will not fail due to safety issues. In such an event, we might need to abandon development of ALD403. Clazakizumab may also fail due to safety issues, causing BMS to cease development.

The manufacture of our product candidates is complex and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped.

The process of manufacturing our products is complex, highly-regulated and subject to multiple risks. The manufacture of biologics involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells and harvesting and purifying the biologic produced by them. As a result, the cost to manufacture biologics is generally far higher than traditional small molecule chemical compounds, and the biologics manufacturing process is less reliable and is difficult to reproduce. Manufacturing biologics, such as Clazakizumab and ALD403, is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We utilize third-party contract manufacturers to produce ALD403 and BMS currently also uses third-party contract manufacturers to produce Clazakizumab using our proprietary yeast production technology.

The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. There are risks associated with scaling-up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. Even if we or our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our or our collaborators' manufacturers are unable to produce sufficient quantities of an approved product for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

ALD403 is currently produced for us by a third-party contract manufacturer using a small-scale process that would not support commercialization of ALD403. We are in the process of transferring our manufacturing processes to this manufacturer. Scaling up a biologic manufacturing process is a difficult and uncertain task, and we may not be successful in transferring our production system or the manufacturer may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale-up the manufacturing process for ALD403 with our current manufacturer, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for ALD403 or other product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacture an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

Even though Clazakizumab has been administered to over 1,000 patients, the MabXpress production system is a non-traditional antibody production platform and as BMS produces product in commercial quantities, BMS may experience unforeseen safety or other manufacturing issues which would adversely affect the commercialization of Clazakizumab.

Even if our product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including the following:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side-effects;
- the price we or our collaborators charge for our products;
- the availability of third-party coverage or reimbursement;
- 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 new therapies; and
- the size and effectiveness of our sales, marketing and distribution support.

If our product candidates are approved and do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable on a sustained basis.

We currently have no sales or distribution personnel or infrastructure and only limited marketing capabilities. If we are unable to develop a sales, marketing and distribution infrastructure on our own or through collaborations or other marketing arrangements, we will not be successful in commercializing ALD403 or other future products.

We do not currently have sales or distribution capabilities and have limited experience in the sale, marketing and distribution of therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We plan to establish a sales force in the United States targeting high-prescribing neurologists and headache centers and work with collaborators in international markets to commercialize ALD403 globally, if it is approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we do not have another product to sell in the same specialty market.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

If we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborators might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in our products, even if our product candidates obtain regulatory approval.

Our and our collaborators' ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The primary focus in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we or our collaborators commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we or our collaborators obtain approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we or our collaborators may not be able to successfully commercialize any product that has been approved.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our or our collaborators' costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our or our collaborators' costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our or our collaborators' inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for newly developed products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We may not be successful in our efforts to use and enhance our proprietary antibody platform to create a pipeline of product candidates and develop commercially successful products.

We are using our proprietary antibody platform for the selection and manufacturing of monoclonal antibodies. We used this platform to create our two lead product candidates, Clazakizumab and ALD403, as well as the other future product candidates that we are currently evaluating. We are at an early stage of development and our platform has not yet, and may never, lead to approved or commercially successful products. Even if we are successful in continuing to build our pipeline, the future product candidates that we evaluate may not be suitable for clinical development, including as a result of their harmful side-effects, limited efficacy or other characteristics that make it unlikely such product candidates will receive regulatory approval or achieve commercial success. If we do not successfully develop and commercialize product candidates using our proprietary antibody platform, we may not be able to obtain product or collaboration revenues in future periods, which would harm our business and prospects.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we or our collaborators may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical trials or cancellation of trials;
- significant costs to defend the related litigation;
- substantial monetary awards;
- loss of revenues; and
- the inability to commercialize any products that we may develop.

We currently have $20 million in product liability insurance coverage for our clinical trials, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We may expend our limited resources to pursue a particular product candidate or disease and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our research programs and product candidates for a specific disease. As a result, we may forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific diseases may not yield any commercially viable products.

If we do not accurately evaluate the commercial potential for a particular product candidate in the right disease, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

We are dependent on BMS for the successful development and commercialization of Clazakizumab for the treatment of RA and other diseases. If BMS does not devote sufficient resources to Clazakizumab's development, is unsuccessful in its efforts, or chooses to terminate its agreement with us, our business, operating results and financial condition will be seriously harmed.

We have entered into a collaboration agreement with BMS to develop and commercialize Clazakizumab. Pursuant to the BMS agreement, responsibility for all clinical and other product development activities and for manufacturing Clazakizumab outside of cancer has been transferred to BMS.

BMS is currently developing Clazakizumab for the treatment of RA and PsA. Should we disagree with BMS about the clinical development or commercialization strategy it employs, we have no rights to impose our clinical development or commercialization strategy on BMS. Similarly, BMS may decide to seek regulatory approval for, and limit commercialization of Clazakizumab, to narrower indications than we would pursue. Unless the collaboration with BMS is terminated, we are not allowed to develop Clazakizumab or any other compound that binds to IL-6 ourself for any indication except cancer. The BMS collaboration may not be clinically or commercially successful due to a number of important factors, including the following:

- Subject to the terms of our collaboration agreement, BMS has wide discretion in determining the efforts and resources that it will apply to its partnership with us. The timing and amount of any development milestones, and downstream commercial milestones and royalties that we may receive under such partnership will depend on, among other things, the efforts, allocation of resources and successful development and commercialization of Clazakizumab.
- BMS may select a dose for Clazakizumab that does not have a favorable benefit/risk profile.
- BMS may develop and commercialize, either alone or with others, products that are similar to or competitive with Clazakizumab.
- BMS's commercialization of Clazakizumab may be affected by other products, such as Orencia, that BMS currently markets for RA.
- BMS may terminate its partnership with us without cause and for circumstances outside of our control, which could make it difficult for us to attract new strategic partners or adversely affect how we are perceived in scientific and financial communities.
- BMS may develop or commercialize Clazakizumab in a way that exposes us to potential litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.
- BMS may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements, which may or may not be related to Clazakizumab.

If BMS were to breach our collaboration agreement, we may need to enforce our rights under the agreement, which could be costly. If we were to terminate our agreement with BMS due to BMS's breach or if BMS were to terminate the agreement without cause, there could be a delay in the return of our rights to Clazakizumab and the development and commercialization of Clazakizumab would be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization on our own.

BMS may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or other change in control, which could divert the attention of its management and adversely affect BMS's ability to retain and motivate key personnel who are important to the continued development of the Clazakizumab program. In addition, the third party to any such transaction could reprioritize BMS's development programs which could delay or cease the development of our programs or cause BMS to terminate the agreement.

If we do not successfully enter into future collaborations for the development and commercialization of product candidates in international markets our business may be harmed.

We may choose to enter into collaboration agreements with third parties with respect to our product candidates, including ALD403, for their development and commercialization in international markets. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates, such as our collaboration with BMS, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of any future collaboration could result in delayed development of product candidates, increased cost to develop product candidates or terminated of development of a product candidate.

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

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. Furthermore, some of the sites for our clinical trials are outside the United States. The performance of these sites may be adversely affected by various issues, including less advanced medical infrastructure, lack of familiarity with conducting clinical trials in accordance with U.S. standards, insufficient training of personnel, communication difficulties or change in local regulations. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, including our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We also rely on other third parties to store and distribute supplies for our clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenues.

We rely on third-party contract manufacturing organizations, or CMOs, to manufacture and supply our product candidate, ALD403. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers and may also face delays in the development and commercialization of our product candidates.

We currently do not own manufacturing facilities for clinical-scale manufacturing of our product candidates and we rely upon third-party CMOs to manufacture and supply drug product for our clinical trials. The manufacture of pharmaceutical products in compliance with the FDA's current good manufacturing practices, or cGMP, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide study drugs in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

All manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation.

We currently rely on Fujifilm Diosynth Biotechnologies and Ajinomoto Althea Inc. to manufacture and provide us with clinical supplies of ALD403. Our agreements do not provide for an entire supply of the drug product necessary for all anticipated clinical trials or for full-scale commercialization. If we and our suppliers cannot agree to the terms and conditions for provision of the drug product necessary for our clinical and commercial supply needs, or if either terminates their agreement in response to a breach by us or otherwise becomes unable to fulfill its supply obligations, our clinical trials could be delayed until a qualified alternative supplier is identified, the manufacturing process is qualified and validated and we have agreed on the terms and conditions for such alternative supplier to supply product for us, which would delay the development and impair the commercialization of ALD403. ALD403 is a biologic and therefore requires a complex production process. Transferring the production process to a new manufacturer would be particularly difficult, time-consuming and expensive and may not yield comparable product. Although alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities necessary to manufacture ALD403 and any other product candidates we may develop is limited, and may be expensive and take a significant amount of time to arrange for alternative suppliers. New suppliers of any product candidate would be required to qualify under applicable regulatory requirements. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results have fluctuated in the past and may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments, and we expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. Accordingly, our revenues will depend on development funding and the achievement of development and clinical milestones under our existing collaboration arrangements, as well as any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

Our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; and
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates.

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

Our future success depends on our ability to retain our senior executive officers and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our senior executive officer and the other principal members of our executive and scientific teams, particularly our President and Chief Executive Officer, Randall C. Schatzman, our Chief Scientific Officer, John A. Latham, our Chief Business Officer, Mark J. Litton, our Senior Vice President Translational Medicine, Jeffrey T.L. Smith, and our Senior Vice President, Finance, Larry K. Benedict. The employment of our executive officers is at-will and our executive officers may terminate their employment with us at any time. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. Although we maintain "key person" insurance for Drs. Schatzman, Latham, Litton and Smith, any insurance proceeds we may receive under our "key person" insurance would not adequately compensate us for the loss of their services.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Although, to date, we have not experienced problems attracting and retaining highly qualified personnel, our industry has experienced a high rate of turnover of management personnel in recent years. 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 employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

As of March 31, 2014, we had 77 employees. Over the next several years, if our product candidates receive marketing approval, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, sales and marketing and other functional areas, including finance, accounting and legal. For example, if ALD403 is approved, we plan to build a 75 to 100 person sales force targeting high-prescribing neurologists and headache centers in the United States. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources 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 physical 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

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

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

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may divert resources away from our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Business disruptions could harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters is located in Washington and certain clinical sites for our product candidates, operations of our existing and future partners and suppliers are or will be located in Washington near major earthquake faults. The ultimate impact on us, our significant partners, suppliers and our general infrastructure of being located near major earthquake faults and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake or other natural or manmade disaster.

Marketing approval of our product candidates in international markets will subject us to additional costs and a variety of risks associated with international operations.

We intend to pursue marketing approvals for our product candidates in international markets directly or with partners and will be subject to additional costs and additional risks related to international operations, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Our ability to use our net operating loss and tax credit carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2013, we had U.S. net operating loss carryforwards, or NOLs, of $87.8 million, which may be used to offset future taxable income or offset income taxes due. In addition, we have U.S. research and development tax credit carryforwards of $4.7 million. These NOLs and tax credit carryforwards expire in various years beginning in 2024, if not utilized. Utilization of the NOLs and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership change rules pursuant to Sections 382 and 383 of the Internal Revenue Code. We performed a section 382 ownership analysis through 2009 and determined that an ownership change occurred in 2005. Based on the analysis performed, however, we do not believe that the Section 382 annual limitation will impact our ability to utilize the tax attributes that existed as of the date of the ownership change in a material manner. We have not completed a study to determine the impact of our IPO, the impact of our private placement in 2012 or the impact of other transactions which have occurred since the 2009 analysis, on our NOLs and tax credit carryforwards under Sections 382 and 383 of the Code. If we have experienced an ownership change in the past or will experience an ownership change as a result of future changes in our stock ownership, some of which changes are outside our control, the tax benefits related to the NOLs and tax credit carryforwards may be further limited or lost.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

We may engage in future acquisitions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may evaluate various strategic transactions, including licensing or acquiring complementary products, technologies or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation of operations and products, retention of key employees, diversion of our management's attention and uncertainties in our ability to maintain key business relationships of the acquired entities. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to Intellectual Property

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to intellectual property license agreements with third parties. For example, we have a third-party royalty free license associated with the Keck Graduate Institute for MabXpress, our yeast-based proprietary manufacturing technology. We may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, royalty payment, milestone payment, insurance and other obligations on us. If we fail to comply with these obligations or our other obligations in our license agreements, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product or use any platform technology that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business.

Our ability to successfully commercialize our products may be impaired if we are unable to obtain and maintain effective intellectual property rights for our proprietary antibody platform and product candidates.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary antibody platform and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents or enforce the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated. Because certain intellectual property rights are shared between us and our collaborators, it is possible that disputes may arise related to the distribution of those rights.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. 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. The standards that the United States Patent and Trademark Office, or USPTO, uses to grant patents are not always applied predictably or uniformly and can change. Consequently, we cannot be certain as to whether pending patent applications will be allowed; and if allowed, we cannot be certain as to the type and extent of patent claims that will be issued to us in the future. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Under our collaboration agreement with BMS, we are obligated to use commercially reasonable efforts to file and prosecute patent applications, and maintain patents, covering Clazakizumab in specified jurisdictions, and the U.S. patent rights are exclusively licensed to BMS and the non-U.S. patent rights are jointly owned by us and BMS.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products 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 or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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 at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

In March 2013, the United States converted to a first-to-file patent system under the recently enacted America Invents Act. With this change, the United States patent system was brought into closer conformity with the patent systems of other countries, the vast majority of which operate as first-to-file patent systems. Under the former system, and assuming the other requirements for patentability were met, the first to conceive of the claimed invention was entitled to the patent. A number of our patents and patent applications are subject to the first-to-invent system because they originated prior to the March 2013 cutoff. Under the new United States system, and outside the United States, the first to file a patent application is entitled to the patent, with certain exceptions. A number of our patents and patent applications are subject to the new first-to-file system in the United States because they originated after the March 2013 cutoff. The full effect of these changes remains unclear as the USPTO endeavors to implement various regulations concerning the new system. Furthermore, the courts have yet to address the vast majority of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. We may become involved in opposition, interference, or derivation proceedings challenging our patent rights or the patent rights of others, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Even if our owned and 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. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of future product 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 or otherwise provide us with a competitive advantage.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Inequitable conduct is frequently raised as a defense during intellectual property litigation. It is believed that all parties involved in the prosecution of our patent applications have complied with their duties of disclosure in the course of prosecuting our patent applications, however, it is possible that legal claims to the contrary could be asserted if we were engaged in intellectual property litigation, and the results of any such legal claims are uncertain due to the inherent uncertainty of litigation. If a court determines that any party involved in the prosecution of our patents failed to comply with their duty of disclosure, the subject patent would be unenforceable. 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.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. We are aware of third-party patents and patent applications containing granted claims relating to CGRP antibodies and the therapeutic use of CGRP antibodies to treat conditions including migraine. Furthermore, since patent applications are published some time after filing, and because applications can take several years to issue, there may be additional currently pending third- party patent applications that are unknown to us, which may later result in issued patents. Because of the inevitable uncertainty in intellectual property litigation, we could lose a patent infringement action asserted against us regardless of our perception of the merits of the case. If we are found to infringe upon a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations.

We may be unable to protect the confidentiality of our trade secrets, thus harming our business and competitive position.

In addition to our patented technology and products, we rely upon trade secrets, including unpatented know- how, technology and other proprietary information to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees, collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. However, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Furthermore, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. Our trade secrets can be lost through their inadvertent or advertent disclosure to others. In addition, intellectual property laws in foreign countries may not protect our intellectual property to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and harm our business.

We may be subject to claims that our employees have wrongfully used or disclosed intellectual property of their former employers. Intellectual property litigation or proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, 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 our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could impair our ability to compete in the marketplace.

Risks Related to Government Regulation

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaboration partners are permitted to market our product candidates in the United States until we receive approval of a BLA from the FDA. Neither we nor our collaboration partners have submitted an application or received marketing approval for any of our product candidates. Obtaining approval of BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we and our collaboration partners believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our product candidates to humans may produce undesirable side-effects, which could interrupt, delay or cause suspension of clinical trials of our product candidates and result in the FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications.

Regulatory approval of BLA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate.

The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

- a product candidate may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA might not approve our or our third-party manufacturers' processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If any of our product candidates fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, our business will be harmed.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up trials to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Furthermore, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products and our business may suffer.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We may seek a distribution and marketing partner for ALD403 outside the United States and may market future products in international markets. In order to market our future products in the European Economic Area, or EEA, and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

Before granting the MA, the European Medicines Agency, or EMA, or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things:

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs," effective 2011;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning January 2011; and
- creates a process for approval of biologic therapies that are similar or identical to approved biologics.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety. We cannot assure that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by the sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 1, 2013, the sequestration went into effect.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

Furthermore, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance and/or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has fluctuated in the past and is likely to be volatile in the future. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- introductions and announcements of future product candidates by us, our collaborators, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to discover, acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our collaborators;
- manufacturing disruptions;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including litigation matters and our ability to obtain patent protection for our product candidates;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- changes in our board of directors or key personnel;
- the expiration of contractual lock-up agreements;
- changes in our capital structure, such as future issuances of debt or equity securities;
- short sales, hedging and other derivative transactions involving our capital stock;
- general economic, industry and market conditions in the United States and abroad;
- other events or factors, including those resulting from war, incidents of terrorism or responses to these events; and
- the other risks described in this "Risk Factors" section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could harm our business.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

As of June 9, 2014, we had outstanding 30,803,668 shares of common stock, of which 23,081,272 shares are currently restricted as a result of securities laws or lock-up agreements with the underwriters that prevent the holders of such shares from offering, selling, contracting to sell, pledging, or otherwise disposing (indirectly or otherwise) of any shares of our common stock or any securities convertible into or exchangeable for shares of our common stock, or entering into any swap hedge or other arrangements, subject to specified exceptions, for a period of 180 days after May 7, 2014. Our underwriters may, in their sole discretion, at any time, release all or any portion of the shares from the restrictions in this agreement Moreover, holders of an aggregate of up to 20,914,137 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above.

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 depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to stockholders for approval.

As of June 9, 2014, our executive officers and directors and their respective affiliated stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing approximately 51% of our common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, will control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire, which in turn could depress our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

An active trading market for our common stock may not be maintained.

Our stock is currently traded on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market on NASDAQ or any other exchange in the future. If an active market for our common stock is not maintained, it may be difficult for our stockholders to sell shares purchased in this offering without depressing the market price for the shares or at all.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we intend take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. 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 this offering, (b) in which we have total annual gross revenue of at least $1.0 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 securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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 avail ourselves of this exemption, and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies" until these standards apply to private companies.

Complying with the laws and regulations affecting public companies will increase our costs and the demands on management and could harm our operating results.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and The NASDAQ Stock Market impose numerous requirements on public companies, including requiring changes in corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These burdens may increase as new legislation is passed and implemented, including any new requirements that the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 may impose on public companies. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. We estimate that we will incur approximately $1.5 million to $2.5 million in incremental costs per year associated with being a publicly traded company, although it is possible that our actual incremental costs will be higher than we currently estimate. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and in the future we may be required to accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, beginning January 1, 2014, Section 404 of the Sarbanes-Oxley Act, or Section 404, requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. As an "emerging growth company," we expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Provisions in our corporate charter documents could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to elect directors to fill a vacancy created by the expansion of the 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;
- our stockholders may not act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock; the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Provisions under Delaware law and Washington law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

In addition to provisions in our corporate charter and our bylaws, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any holder of at least 15% of our capital stock for a period of three years following the date on which the stockholder became a 15% stockholder. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a "target corporation" from engaging in any of a broad range of business combinations with any stockholder constituting an "acquiring person" for a period of five years following the date on which the stockholder became an "acquiring person."

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

(a) Sales of Unregistered Securities

From January 1, 2014 to March 31, 2014, we granted stock options under our 2005 Stock Option Plan to purchase 12,726 shares of our common stock to certain of our directors at an exercise price of $6.33 per share. In addition, from January 1, 2014 to March 31, 2014, we granted stock options under our 2005 Stock Option Plan to purchase 114,669 shares of our common stock to certain of our employees at an exercise price of $6.77 per share. During such period we issued an aggregate of 24,814 shares of common stock that were not registered under the Securities Act pursuant to the exercise of stock options for cash consideration with aggregate exercise proceeds of approximately $34,000. These issuances were undertaken in reliance upon the exemption from registration requirements available under Rule 701 of the Securities Act.

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

On May 7, 2014, our registration statement on Form S-1 (No. 333-194672) was declared effective for our IPO. On May 13, 2014, we issued and sold 8,000,000 shares of our common stock and on May 21, 2014, we issued and sold 875,396 shares of our common stock pursuant to the underwriters' partial exercise of their option to purchase additional shares, in each case at a public offering price of $10.00 per share. Credit Suisse Securities (USA) LLC and Leerink Swann LLC acted as joint book-running managers for the offering and Wells Fargo Securities, LLC and Sanford C. Bernstein & Co., LLC acted as co-managers for the offering. Following the sale of the shares in connection with the closings of the IPO, the offering terminated. As a result of the offering, we received total net proceeds of approximately $80.1 million, after deducting total expenses of $8.6 million, consisting of underwriting discounts and commissions of $6.2 million and offering-related expenses of approximately $2.4 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on May 8, 2014. As our IPO closed after the period covered by this quarterly report, none of the proceeds from the IPO were used during the period covered by this quarterly report.

Item 6. Exhibits

Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of Alder BioPharmaceuticals, Inc.
3.2(2)	Amended and Restated Bylaws of Alder BioPharmaceuticals, Inc.
4.1(3)	Amended and Restated Investors' Rights Agreement, dated as of April 16, 2012, by and among Alder BioPharmaceuticals, Inc. and certain of its stockholders.
4.2(2)	Amendment No. 1 to Amended and Restated Investors' Rights Agreement, dated as of April 7, 2014, by and among Alder BioPharmaceuticals, Inc. and certain of its stockholders.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a).
32.1*	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH**	XBRL Taxonomy Extension Schema Document.
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 13, 2014 (File No. 001-36431) and incorporated herein by reference.

(2) Previously filed as an exhibit to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-194672), filed with the Securities and Exchange Commission on April 25, 2014 and incorporated herein by reference.

(3) Previously filed as an exhibit to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-194672), filed with the Securities and Exchange Commission on March 19, 2014 and incorporated herein by reference.

* The Certifications attached as Exhibits 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Alder BioPharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

** Attached as Exhibit 101 to this Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Income (Loss), (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.

Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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.

Alder BioPharmaceuticals, Inc.

Date: June 20, 2014

By: /s/ Randall C. Schatzman
Randall C. Schatzman
President and Chief Executive Officer
(Principal Executive Officer)

Alder BioPharmaceuticals, Inc.

Date: June 20, 2014

By: /s/ Larry K. Benedict
Larry K. Benedict
Senior Vice President, Finance
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Randall C. Schatzman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Alder BioPharmaceuticals, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: June 20, 2014

/s/ Randall C. Schatzman
Randall C. Schatzman
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Larry K. Benedict, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Alder BioPharmaceuticals, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: June 20, 2014

/s/ Larry K. Benedict
Larry K. Benedict
Senior Vice President, Finance
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Randall C. Schatzman, President and Chief Executive Officer of Alder BioPharmaceuticals, Inc. (the "Company"), and Larry K. Benedict, Senior Vice President, Finance of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2014, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: June 20, 2014

In Witness Whereof, the undersigned have set their hands hereto as of the 20th day of June, 2014.

/s/ Randall C. Schatzman	/s/ Larry K. Benedict
Randall C. Schatzman	Larry K. Benedict
President and Chief Executive Officer	Senior Vice President, Finance
(Principal Executive Officer)	(Principal Financial and Accounting Officer)

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