Calithera Biosciences, Inc.
Form 10-Q
November 07, 2018

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 September 30, 2018

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: 001-36644

CALITHERA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	27-2366329
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

343 Oyster Point Blvd., Suite 200

South San Francisco, CA 94080

(Address of principal executive offices including zip code)

Registrant’s telephone number, including area code: (650) 870-1000

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

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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging Growth Company	

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

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

As of November 2, 2018, the registrant had 38,125,716 shares of common stock, $0.0001 par value per share, outstanding.

Calithera Biosciences, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2018

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PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements

Calithera Biosciences, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except per share amounts)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$61,135	$48,475
Short-term investments	80,321	115,318
Receivables from collaborations	1,809	1,142
Prepaid expenses and other current assets	1,553	2,732
Total current assets	144,818	167,667
Long-term investments	—	22,361
Other assets	845	228
Restricted cash	440	440
Property and equipment, net	1,571	1,759
Total assets	$147,674	$192,455
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$517	$1,072
Accrued liabilities	10,088	8,938
Current portion of deferred revenue	—	29,017
Total current liabilities	10,605	39,027
Deferred revenue, less current portion	—	2,028
Deferred rent	1,159	1,093
Total liabilities	11,764	42,148
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value, 200,000 shares authorized as of September 30, 2018 and December 31, 2017; 37,204 and 35,759 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	4	4
Additional paid-in capital	312,751	300,906
Accumulated deficit	(176,671)	(150,333)
Accumulated other comprehensive loss	(174)	(270)

Total stockholders' equity	135,910	150,307
Total liabilities and stock and stockholders' equity	$147,674	$192,455

See accompanying notes.

Calithera Biosciences, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Collaboration revenue	$—	$7,254	$22,254	$18,701
Total revenue	—	7,254	22,254	18,701
Operating expenses:				
Research and development	16,420	10,833	49,218	27,615
General and administrative	3,087	3,074	10,093	9,230
Total operating expenses	19,507	13,907	59,311	36,845
Loss from operations	(19,507)	(6,653)	(37,057)	(18,144)
Interest income, net	658	582	1,927	1,292
Net loss	$(18,849)	$(6,071)	$(35,130)	$(16,852)
Net loss per share, basic and diluted	$(0.52)	$(0.17)	$(0.98)	$(0.53)
Weighted average common shares used to compute net loss per share, basic and diluted	36,405	35,475	36,021	32,072

See accompanying notes.

Calithera Biosciences, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$(18,849)	$(6,071)	$(35,130)	$(16,852)
Other comprehensive gain (loss):				
Net unrealized gain (loss) on available-for-sale securities	77	11	96	(110)
Total comprehensive loss	$(18,772)	$(6,060)	$(35,034)	$(16,962)

See accompanying notes.

Calithera Biosciences, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2018	2017
Cash Flows Provided By (Used In) Operating Activities		
Net loss	$(35,130)	$(16,852)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	375	254
Amortization of premiums (discounts) on investments	(124)	356
Stock-based compensation	5,617	3,968
Loss on disposal of property and equipment	—	6
Changes in operating assets and liabilities:		
Receivables from collaborations	(667)	(2,177)
Prepaid expenses and other current assets	1,179	(2,437)
Other assets	(617)	(468)
Accounts payable	(563)	767
Accrued liabilities	1,164	3,089
Deferred revenue	(22,254)	38,299
Deferred rent, non-current	66	309
Net cash provided by (used in) operating activities	(50,954)	25,114
Cash Flows Provided by (Used In) Investing Activities		
Purchases of investments	(47,292)	(174,357)
Proceeds from maturity of investments	104,870	57,949
Purchases of property and equipment	(184)	(682)
Net cash provided by (used in) investing activities	57,394	(117,090)
Cash Flows Provided By Financing Activities		
Proceeds from issuance of common stock upon public offering, net	—	75,386
Proceeds from issuance of common stock under stock purchase agreement, net	—	7,914
Proceeds from issuance of common stock through an at-the-market offering, net	5,603	36,907
Proceeds from stock option exercises and employee stock plan purchases	617	973
Net cash provided by financing activities	6,220	121,180
Net increase in cash, cash equivalents, and restricted cash	12,660	29,204
Cash, cash equivalents, and restricted cash at beginning of period	48,915	10,647
Cash, cash equivalents, and restricted cash at end of period	$61,575	$39,851
Supplemental Disclosure of Non-Cash Investing and Financing Information:		
Change in unpaid amounts related to property and equipment purchases	$3	$51
Change in unpaid amounts related to deferred financing costs	$8	$46

See accompanying notes.

Calithera Biosciences, Inc.

Notes to Condensed Consolidated Financial Statements

1. Organization and Basis of Presentation

Organization

Calithera Biosciences, Inc. (the "Company") was incorporated in the State of Delaware on March 9, 2010. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing small molecule drugs that target novel and critical metabolic pathways in tumor and cancer-fighting immune cells. The Company's principal operations are based in South San Francisco, California, and it operates in one segment.

Presentation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Calithera Biosciences UK Limited. All significant intercompany accounts and transactions have been eliminated from the condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The interim condensed consolidated balance sheet as of September 30, 2018, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, and the statements of cash flows for the nine months ended September 30, 2018 and 2017 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed consolidated financial statements included in this report. The financial data and the other information disclosed in these notes to the condensed consolidated financial statements related to the nine-month periods are also unaudited. The results of operations for the nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The balance sheet as of December 31, 2017 included herein was derived from the audited consolidated financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Form 10-K as filed with the Securities and Exchange Commission ("SEC").

Use of Estimates

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to clinical trial accrued liabilities, revenue recognition, fair value of marketable securities, income taxes, and stock-based compensation. Management bases its estimates on historical experience and on various other market specific and relevant assumptions that management

believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents, which consist primarily of amounts invested in money market accounts, are stated at fair value.

Investments

All investments have been classified as “available-for-sale” and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments at the time of purchase and reevaluates such designation as of each balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest income, net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in interest income, net.

Restricted Cash

Restricted cash consists of money market funds held by the Company's financial institution as collateral for the Company's obligations under its facility lease for the Company's corporate headquarters in South San Francisco, California.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, investments and restricted cash. The Company invests in a variety of financial instruments and, by its policy, limits these financial instruments to high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies and highly rated banks and corporations, subject to certain concentration limits. The Company's cash, cash equivalents, investments and restricted cash are held by financial institutions in the United States that management believes are of high credit quality. Amounts on deposit may at times exceed federally insured limits.

All of the Company's collaboration revenue and the majority of the Company's receivables from collaborations are derived from its collaboration and license agreement with Incyte Corporation, or Incyte, as described in Note 9, Collaboration and Licensing Agreements - Incyte Collaboration and License Agreement.

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification, or ASC No. 2014-09, Revenue from Contracts with Customers (Topic 606), or ASC 606, using the modified retrospective approach. Under this approach, the Company recorded a cumulative adjustment to decrease accumulated deficit and deferred revenue by $8.8 million. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company has a collaboration and license agreement with Incyte, or the Incyte Collaboration Agreement, that is within the scope of ASC 606, under which it licenses certain rights to one of its product candidates to Incyte Corporation. The terms of this arrangement include payment to the Company of a non-refundable, upfront license fee, and potential development, regulatory and sales milestones, and sales royalties. Each of these payments results in collaboration revenues, except for revenues from royalties on net sales of licensed products, which would be classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreement, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the

Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract.

Licenses of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promised goods or services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

The following table summarizes the impact of adopting ASC 606 on select unaudited condensed statement of operations line items for the nine months ended September 30, 2018 (in thousands, except per share data):

Nine Months Ended September 30, 2018	As Reported	Adjustments	Balances Without the Adoption of ASC 606
Collaboration revenue	$ 22,254	$ 8,791	$ 31,045
Total revenue	22,254	8,791	31,045
Loss from operations	(37,057)	8,791	(28,266)
Net loss	(35,130)	8,791	(26,339)

Contract Balances

Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional.

The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

The following table presents changes in the Company's contract assets and liabilities for the nine months ended September 30, 2018 (in thousands):

Nine Months Ended September 30, 2018	Balance at Beginning of Period	Balance at End of Period
Contract liabilities:		
Deferred revenue	$ 29,017	$ —
Deferred revenue, less current portion	2,028	—

Deferred revenue related to the Incyte Collaboration Agreement, which was comprised of the $57 million transaction price including a $45 million upfront license payment and a $12 million development milestone achieved, less the collaboration revenue recognized from the effective date of the contract, was recognized as the combined performance obligation was satisfied.

The Company had no contract assets as of September 30, 2018. During the nine months ended September 30, 2018, the Company's contract liabilities, which consisted of deferred revenue, decreased $31.0 million for the nine months ended September 30, 2018, related to revenue recognized in the period related to amounts included in the contract liability at the beginning of the period. In addition, the Company recorded a cumulative adjustment to decrease accumulated deficit and deferred revenue by $8.8 million upon the adoption of ASC 606 on January 1, 2018, using the modified retrospective approach. For the three and nine months ended September 30, 2018, the Company did not recognize any revenue from performance obligations satisfied in previous periods.

Accrued Research and Development Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and includes these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the consolidated statements of operations. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period without consideration of common stock equivalents. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued a comprehensive new standard on revenue from contracts with customers, ASC 606. The standard's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. In 2016, the FASB updated the guidance for reporting revenue gross versus net to improve the implementation guidance on principal versus agent considerations, and for identifying performance obligations and the accounting of intellectual property licenses. In addition, the FASB introduced practical expedients and made narrow scope improvements to the new accounting guidance.

The Company adopted the accounting standard update on January 1, 2018 using the modified retrospective approach for its collaboration and license agreement with Incyte. Therefore, comparative information was not adjusted and the impact of the transition is reflected in opening accumulated deficit. The consideration the Company is eligible to receive under this agreement includes upfront payments, research and development funding, milestone payments, and sales-based royalties. The new revenue recognition standard differs from the previous accounting in many respects, such as in the accounting for variable consideration and the measurement of progress toward completion of performance obligations. The most significant impact of the standard relates to the Company's method of revenue

recognition for performance obligations that are delivered over time. Under the new standard, milestone payments are included in the transaction price as variable consideration, subject to a constraint, and are allocated to the performance obligations in the contract. Therefore, the milestone payments are recognized over the performance period rather than when achieved. In addition, legacy guidance permitted straight-line recognition of revenue for performance obligations that are delivered over time. The new standard requires an entity to recognize revenue based on the pattern of transfer of the services. The impact of adoption resulted in the Company recording an adjustment to decrease the accumulated deficit and deferred revenue by $8.8 million at January 1, 2018 to reflect revenue being recognized based on a measurement of progress toward completion of the combined performance obligation, rather than on a straight-line basis.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which is aimed at making leasing activities more transparent, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU is effective for all interim and annual reporting periods beginning after December 15, 2018 with early adoption permitted and was previously required to be applied with a modified retrospective approach to each prior reporting period presented. In July 2018, the FASB issued ASU No. 2018-11,

Leases (Topic 842): Targeted Improvements, or ASU No. 2018-11. In issuing ASU No. 2018-11, the FASB is permitting another transition method for ASU 2016-02, which allows the transition to the new lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is finalizing its assessment of the impact of adoption and anticipates electing this new transition method when it adopts the new standard effective January 1, 2019.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash Payments, or ASC 230, to clarify how entities should present restricted cash and restricted cash equivalents in their statements of cash flows. Under this update, entities are required to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in their statements of cash flows. The Company adopted this standard on January 1, 2018 retrospectively. The adoption of this standard did not impact the Company's unaudited condensed consolidated balance sheets, statements of operations, or statements of comprehensive loss. The following table summarizes the impact of adopting ASC 230 on select unaudited condensed statement of cash flows line items (in thousands) for the nine months ended September 30, 2017:

	As Originally Reported	Adjustments	Balances With the Adoption of ASC 230
Change in restricted cash	$(394)	$ 394	$—
Net cash provided by (used in) investing activities	(117,484)	394	(117,090)
Net increase in cash, cash equivalents and restricted cash*	28,810	394	29,204
Cash, cash equivalents and restricted cash at beginning of period*	10,601	46	10,647
Cash, cash equivalents and restricted cash at end of period*	39,411	440	39,851

*For the nine months ended September 30, 2017, this line item, as originally reported, excluded restricted cash.

The Tax Cuts and Jobs Act, or Tax Act, was enacted on December 22, 2017 and provides for significant changes to U.S. tax law. Among other provisions, the Act reduces the U.S. corporate income tax rate to 21%, effective in 2018. As a result, the Company remeasured its U.S. deferred tax assets and liabilities as of December 31, 2017 based on the reduction of the U.S. federal corporate tax rate from 35% to 21% and assessed the realizability of its deferred tax assets based on its understanding of the provisions of the new law. The remeasurement resulted in an estimated one-time reduction in deferred tax assets of $17.8 million as of December 31, 2017, which was fully offset by a corresponding change to the Company's valuation allowance.

In March 2018, the FASB issued ASU No. 2018-05 – Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118, or SAB 118, which provides guidance on accounting for the Tax Act, and provides a measurement period should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting. In accordance with this guidance, the Company considers its accounting for the impacts of the new tax law to be provisional. During the three and nine months ended September 30, 2018, no additional measurement-period adjustments were made by the Company related to the Tax Act. The Company continues to assess the impact of the recently enacted tax law and associated guidance on its business and consolidated financial statements and plans to complete its accounting for the income tax effects of the Tax Act within the one-year measurement period in 2018.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The ASU also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Revenue from

Contracts with Customers (Topic 606). The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company is currently assessing the effect that the ASU will have on its financial position, results of operations, and disclosures.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the condensed consolidated financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, investments, receivables from collaborations, accounts payable, accrued liabilities and the current portion of deferred revenue that approximate fair value due to their relatively short maturities.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

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

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds as Level 1. When quoted market prices are not available for the specific security, then the Company estimates fair value by using quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third party data providers, including but not limited to, benchmark yields, interest rate curves, reported trades, broker/dealer quotes and market reference data. The Company classifies its corporate notes and U.S. government agency securities as Level 2. Level 2 inputs for the valuations are limited to quoted prices for similar assets or liabilities in active markets and inputs other than quoted prices that are observable for the asset or liability. There were no transfers between Level 1 and Level 2 during the periods presented.

The following table sets forth the fair value of our financial assets and liabilities, allocated into Level 1, Level 2 and Level 3, that was measured on a recurring basis (in thousands):

	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$15,160	$—	$ —	$15,160
Corporate notes and commercial paper	—	78,241	—	78,241
U.S. treasury securities	—	13,936	—	13,936
U.S. government agency securities	—	33,301	—	33,301
Total financial assets	$15,160	$125,478	$ —	$140,638

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$12,430	$—	$ —	$12,430
Corporate notes and commercial paper	—	85,492	—	85,492
U.S. treasury securities	—	34,437	—	34,437

U.S. government agency securities	—	53,691	—	53,691
Total financial assets	$12,430	$173,620	$ —	$186,050

4. Financial Instruments

Cash equivalents and investments, all of which are classified as available-for-sale securities and restricted cash, consisted of the following (in thousands):

	September 30, 2018				December 31, 2017			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$15,160	$ —	$ —	$15,160	$12,430	$ —	$ —	$12,430
Corporate notes and commercial paper	78,279	—	(38)	78,241	85,553	—	(61)	85,492
U.S. treasury securities	13,949	—	(13)	13,936	34,505	—	(68)	34,437
U.S. government agency securities	33,423	—	(122)	33,301	53,832	—	(141)	53,691
	$140,811	$ —	$ (173)	$140,638	$186,320	$ —	$ (270)	$186,050
Classified as:								
Cash equivalents				$59,877				$47,931
Short-term investments				80,321				115,318
Long-term investments				—				22,361
Restricted cash				440				440
Total cash equivalents, restricted cash and investments				$140,638				$186,050

At September 30, 2018, the remaining contractual maturities of available-for-sale securities were less than one year. There have been no significant realized gains or losses on available-for-sale securities for the periods presented. As of September 30, 2018, unrealized losses on cash equivalents and investments were $173,000 and the losses were deemed to be temporary. The gross unrealized loss that had been in a continuous loss position for 12 months or longer was $0.1 million as of September 30, 2018. There were no investments in a continuous loss position for 12 months or longer as of December 31, 2017. The Company does not intend to sell its securities that are in an unrealized loss position, and it is unlikely that the Company will be required to sell its securities before recovery of their amortized cost basis, which may be maturity. Factors considered in determining whether a loss is temporary include the length of time and extent to which the fair value has been less than the amortized cost basis and whether the Company intends to sell the security or whether it is more likely than not that the Company would be required to sell the security before recovery of the amortized cost basis. As of September 30, 2018, the Company had a total of $141.9 million in cash, cash equivalents, restricted cash and investments, which includes $1.3 million in cash and $140.6 million in cash equivalents, restricted cash and investments.

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued bonus and payroll expenses	$ 3,190	$ 3,016
Accrued professional and consulting services	282	367
Accrued clinical and manufacturing expenses	5,960	4,845
Accrued preclinical and research expenses	458	469
Other	198	241
Total accrued liabilities	$ 10,088	$ 8,938

6. Stockholders' Equity

At-the-Market Offering

In August 2017, the Company entered into a sales agreement with Cowen, as sales agent and underwriter, pursuant to which the Company could issue and sell shares of its common stock with an aggregate maximum offering price of $50.0 million under an at-the-market offering program ("ATM program"). The Company will pay Cowen up to 3% of gross proceeds for any common stock sold through the sales agreement. During the nine months ended September 30, 2018, the Company sold an aggregate of 1,201,464 shares at an average price of approximately $4.89 per share for gross proceeds of $5.9 million, resulting in net proceeds of $5.6 million after underwriting fees and offering expenses. As of September 30, 2018, $42.5 million of common stock remained available for sale under the ATM program.

7. Stock Based Compensation

A summary of stock option activity is as follows (in thousands, except weighted-average exercise price and contractual term amounts):

	Options Outstanding			
	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding — December 31, 2017	3,571	$ 7.67		
Options granted	1,160	$ 8.13		
Options exercised	(125)	$ 1.97		
Options cancelled	(72)	$ 8.09		
Outstanding — September 30, 2018	4,534	$ 7.94	7.79	$ 3,001
Exercisable — September 30, 2018	2,329	$ 7.97	6.94	$ 1,946

Total stock-based compensation expense related to the Company's 2010 Equity Incentive Plan, 2014 Equity Incentive Plan and the 2014 Employee Stock Purchase Plan was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$1,013	$766	$3,021	$2,115
General and administrative	803	699	2,596	1,853
Total stock-based compensation	$1,816	$1,465	$5,617	$3,968

8. Net Loss per Share

Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive.

Potentially dilutive securities that were not included in the diluted net loss per share calculations because they would be anti-dilutive were as follows (in thousands):

	September 30,	
	2018	2017
Options to purchase common stock	4,534	3,542
Employee stock plan purchases	116	93
Total	4,650	3,635

9. Collaboration and Licensing Agreements

Incyte Collaboration and License Agreement

On January 27, 2017, the Company entered into a collaboration and license agreement with Incyte (the “Incyte Collaboration Agreement”). Under the terms of the Incyte Collaboration Agreement, the Company granted Incyte an exclusive, worldwide license to develop and commercialize its small molecule arginase inhibitors for hematology and oncology indications. The parties are collaborating on and co-funding the development of the licensed products, with Incyte bearing 70% and the Company bearing 30% of global development costs. The parties will share profits and losses in the United States, with 60% to Incyte and 40% to the Company. The Company will have the right to co-detail the licensed products in the United States, and Incyte will pay the Company tiered royalties ranging from the low to mid-double digits on net sales of licensed products outside the United States. The Company may opt out of its co-funding obligation, in which case the United States profit sharing will no longer be in effect, and Incyte will pay the Company tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the United States and outside the United States, and additional royalties to reimburse the Company for previously incurred development costs.

Under the Incyte Collaboration Agreement, the Company received an upfront payment of $45.0 million in February 2017. In March 2017, the Company achieved a development milestone of $12.0 million, for which the Company received payment in May of

2017. The Company is also eligible to receive up to an additional $418.0 million in potential development, regulatory and sales milestones. Incyte and the Company will share in any future United States net profits and losses, with the Company bearing 40% and Incyte bearing 60%, respectively, and outside the United States the Company will be eligible to receive from Incyte tiered royalties, with rates in the low to mid-teens of sales.

The Incyte Collaboration Agreement also provides that the Company may choose to opt out of its co-funding obligations at any time. In this scenario, the potential development, regulatory and commercialization milestones from Incyte will be up to an additional $738.0 million. The Company would no longer be eligible to receive future United States profits and losses but would be eligible to receive tiered royalty payments on future global sales, including United States sales. In addition, if the Company opts out, the Company will receive an incremental 3% royalty on annual net sales in the United States of such licensed product until such incremental royalty equals 120% of previous development expenditures incurred by the Company.

The Incyte Collaboration Agreement is considered to be under the scope of FASB Topic 808, Collaborative Arrangements. The Company has concluded that the research and development co-funding activities were not representative of a customer relationship and this unit of account is accounted for as an increase to or reduction of research and development expenses, rather than as revenue. The performance obligations under the Incyte Collaboration Agreement consist of intellectual property licenses and the performance of certain manufacturing and manufacturing technology transfer services. The Company has determined that the license is not distinct from the associated manufacturing and technology transfer services to be performed under the agreement. Specifically, the Company believes the license is not capable of being distinct, as Incyte did not have the know-how to manufacture the collaboration product without Calithera's assistance until completion of the manufacturing technology transfer process, and no other third parties could perform such assistance due to the early stage nature of the licensed intellectual property as well as Calithera's propriety knowledge with respect to the licensed intellectual property. Prior to the adoption of ASC 606, the Company concluded that the delivered licenses did not have stand-alone value, and the rights conveyed to Incyte did not permit Incyte to perform all efforts necessary to use the Company's technology to bring the compound through development and, upon regulatory approval, commercialization of the compound, without the associated manufacturing and technology transfer services. Accordingly, the Company combined these deliverables and allocated the upfront consideration of $45.0 million to the combined unit of accounting. The Company recognized the $45.0 million upfront payment on a straight-line basis over the estimated period of performance under the Incyte Collaboration Agreement, and recognized the $12.0 million developmental milestone payment from Incyte on a straight-line basis over the remaining period of performance for the combined unit of accounting. For the three and nine months ended September 30, 2017, the Company recognized revenue from its collaboration with Incyte totaling $7.3 million and $18.7 million, respectively, related to amortization of the $45.0 million upfront fee and the $12.0 million milestone.

Upon the adoption of ASC 606 on January 1, 2018 under the modified retrospective approach, the transaction price was determined to be $57.0 million, representing the $45.0 million upfront payment and the $12.0 million developmental milestone payment from Incyte that was earned in March 2017. The $57.0 million transaction price was recognized over the performance period, based on the measure of progress toward completion for the combined performance obligation, rather than on a straight-line basis. The measure of progress towards completion was based on the effort of certain employees within the Company who dedicated time to complete the manufacturing services and technology transfer to Incyte. As of June 30, 2018, the manufacturing services and technology transfer to Incyte were determined to be substantially complete. For the three and nine months ended September 30, 2018, the Company recognized revenue from its collaboration with Incyte totaling $0 and $22.3 million, respectively, related to the completion of the combined performance obligation.

Net costs associated with co-development activities performed under the agreement are included in research and development expenses in the accompanying unaudited condensed consolidated statements of operations, with any reimbursement of costs by Incyte reflected as a reduction of such expenses. For the three and nine months ended September 30, 2018, net costs reimbursable and/or reimbursed by Incyte were $0.6 million and $3.2 million,

respectively. For the three and nine months ended September 30, 2017, net costs reimbursed by Incyte were $2.0 million and $5.7 million, respectively. As of September 30, 2018, the receivable due from Incyte was $1.7 million.

Symbioscience License Agreement

In December 2014, the Company entered into an exclusive license agreement with Mars, Inc., by and through its Mars Symbioscience division ("Symbioscience"), under which the Company has been granted the exclusive, worldwide license to develop and commercialize Symbioscience's portfolio of arginase inhibitors for use in human healthcare ("Symbioscience License Agreement"). There were no expenses related to its licensing arrangement with Mars Symbioscience recorded in the three and nine months ended September 30, 2018.

The Company may make future payments of up to $23.6 million contingent upon attainment of various development and regulatory milestones and $95.0 million contingent upon attainment of various sales milestones. Additionally, the Company will pay royalties on sales of the licensed product, if such product sales are ever achieved. If the Company develops additional licensed products, after achieving regulatory approval of the first licensed product, the Company would owe additional regulatory milestone payments and additional royalty payments based on sales of such additional licensed products.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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 th 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. We caution investors that our business and financial performance are subject to substantial risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report on Form 10-Q. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into or review of, all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely on these statements.

Overview

We are a clinical-stage pharmaceutical company focused on discovering and developing small molecule drugs that target novel and critical metabolic pathways in tumor and cancer-fighting immune cells. Tumor metabolism and immuno-oncology have emerged as promising new fields for cancer drug discovery, and recent clinical successes with therapeutic agents in each field have created fundamentally new therapies for cancer patients. With our unique approach, we have established a broad pipeline of small molecule drug candidates that target enzymes controlling metabolically critical pathways in tumor cells and tumor-associated immune cells. Two of our compounds are currently in clinical development and two additional compounds from our preclinical pipeline are expected to enter the clinic in 2019. Our product candidate CB-839 is an oral inhibitor of glutaminase, a critical enzyme in tumor cells that controls utilization of the nutrient glutamine. CB-839 is being evaluated in two randomized trials in patients with renal cell carcinoma, or RCC, with data expected from these trials in 2019 and 2020, respectively. Our product candidate, INCB001158, also known as CB-1158, is an oral inhibitor of arginase, an enzyme that depletes the amino acid arginine, a key metabolic nutrient for T cells. INCB001158 is being co-developed with Incyte Corporation, or Incyte, for oncology and hematology indications, and is currently being evaluated in Phase 1/2 trials as a monotherapy and in combination with other anti-cancer agents. Data from INCB001158 is expected to be presented at a medical meeting in the first half of 2019. Arginase inhibitors also have potential in the treatment of cystic fibrosis; accordingly, we have selected CB-280, a unique oral arginase inhibitor, to enter clinical trials in cystic fibrosis patients in 2019. Our next most advanced oncometabolism program targets CD73, an enzyme in the ATP metabolic pathway that plays a critical immunosuppressive role in tumors. We anticipate that our oral CD73 inhibitor will also enter the clinic in 2019.

CB-839

CB-839 is a potent and reversible oral inhibitor of glutaminase, the key enzyme in cells that converts glutamine to glutamate. Many tumor cells depend on this metabolic pathway for growth and survival. CB-839, when given alone or in combination with a variety of other anti-cancer agents, effects multiple pathways in tumor cells, leading to nutritional blocks, inhibition of DNA synthesis, oxidative stress, and cell cycle disruptions. Because CB-839 has multiple mechanisms for impacting cellular metabolism, it has anti-tumor effects on a number of different tumor types using a variety of different agents, including tyrosine kinase inhibitors, mTOR inhibitors, taxanes, cdk4/6 inhibitors and PARP inhibitors. CB-839 binds to a site on glutaminase distinct from the glutamine-binding active site, making it a highly selective and unique allosteric inhibitor. CB-839 is well-tolerated in part because of this selectivity. We believe that CB-839 is the only allosteric glutaminase inhibitor currently in clinical trials.

We are currently developing CB-839 in combination with standard therapies in a select set of solid tumors. Our primary focus is in RCC where we are evaluating CB-839 in two randomized Phase 2 trials, including one with registration intent. CB-839 is also being evaluated in a Phase 1b/2 trial in combination with nivolumab for the treatment of solid tumors. We also plan to initiate two Phase 1/2 clinical studies in the first quarter of 2019, in combination with palbociclib and talazoparib respectively. These trials are part

of a clinical collaboration with Pfizer, announced in October 2018, in which Pfizer will provide palbociclib and talazoparib, as well as financial support.

CB-839 Evaluation in Renal Cell Carcinoma

In January 2018, we presented an update to the Phase 1b trial of CB-839 in combination with everolimus in RCC. Twenty-four RCC patients, with a median of 3 prior therapies, were treated and evaluable for response. 92% of patients experienced disease control, including one patient with a partial response and 21 patients with stable disease. The median progression free survival was 5.8 months, which compares favorably to historical data in this patient population. Patients were administered CB-839 in oral doses that ranged from 400-800 mg twice a day in combination with a fixed oral dose of everolimus at 10 mg once a day. The addition of CB-839 to full-dose everolimus has been well tolerated, with a similar safety profile to the known profile of everolimus alone.

In October 2018, we presented an update to the Phase 1b trial of CB-839 in combination with cabozantinib in RCC. Among 12 evaluable late-line RCC patients treated with CB-839 and cabozantinib, including 10 clear cell patients and two papillary patients, 100% of patients experienced tumor shrinkage and had disease control. The response rate was 50% in the clear cell patient population, which compares favorably to historical data with cabozantinib monotherapy. Patients enrolled in this trial had advanced or metastatic disease and had received a median of three prior treatments, which included tyrosine kinase inhibitors, mTOR inhibitors, and checkpoint inhibitors. Patients were administered CB-839 in oral doses that ranged from 600-800 mg twice a day in combination with a fixed oral dose of cabozantinib at 60 mg once a day.

We are enrolling two Phase 2 randomized clinical trials of CB-839 for the treatment of RCC. The ENTRATA trial is a randomized, double-blind, placebo-controlled trial designed to evaluate the safety and efficacy of CB-839 with everolimus versus everolimus alone in approximately 65 patients with metastatic, clear cell RCC patients who have been treated with at least two prior lines of systemic therapy including a VEGFR-targeting tyrosine kinase inhibitor. Patients are randomized in a 2:1 ratio. The primary endpoint is progression free survival; overall survival will be assessed as a secondary endpoint. The multicenter study opened for enrollment in August 2017 and is being conducted at multiple sites in the United States (NCT03163667). The trial is expected to be fully enrolled in the fourth quarter of 2018 or early 2019, with primary endpoint analysis in 2019.

The CANTATA trial (NCT03428217) is a Phase 2 randomized, placebo-controlled trial comparing CB-839 in combination with cabozantinib versus cabozantinib alone in metastatic clear cell RCC patients who have previously received one or two prior lines of therapy, including a prior anti-angiogenic agent or nivolumab. This trial, originally designed to enroll approximately 300 clear cell renal cell carcinoma patients, has been enlarged to approximately 400 patients. Patients are randomized in a 1:1 ratio. The primary endpoint is progression free survival assessed by independent review; overall survival is a secondary endpoint. Patients will be stratified by International Metastatic Renal Cell Carcinoma Database Consortium, or IMDC, risk category and prior treatment with anti-PD(L)1 therapy. The study has 80% power to show a 35% improvement in progression free survival. In support of the CANTATA trial, Exelixis, Inc. has entered into a material supply agreement with us for cabozantinib. The U.S. Food and Drug Administration, or FDA, has granted Fast Track designation to CB-839 in combination with cabozantinib, for the treatment of patients with metastatic RCC who have received one or two prior lines of therapy, including at least one vascular endothelial growth factor tyrosine kinase inhibitor or the combination of nivolumab and ipilimumab. The CANTATA trial opened for enrollment in April 2018 and is expected to take approximately two years to reach the primary endpoint analysis in 2020.

Evaluation of CB-839 in Combination with the Immunotherapy Agent Nivolumab

In August 2016, we initiated CX-839-004, a Phase 1/2 clinical trial of CB-839 in combination with the PD-1 inhibitor nivolumab in patients with RCC, melanoma, and non-small cell lung cancer, or NSCLC, designed to assess safety, pharmacokinetics, pharmacodynamics and efficacy of the combination.

In November 2017, we presented initial data from the ongoing study of five patient cohorts. The study enrolled three cohorts of patients who have received a checkpoint inhibitor (PD-1/PD-L1) in the most recent line of therapy. Among 16 evaluable melanoma patients, all of whom were progressing on a checkpoint inhibitor at study entry, one patient achieved a complete response and two patients achieved partial responses. The overall response rate in this cohort was 19%, and the overall disease control rate was 44%. Among six evaluable NSCLC patients, all of whom were progressing on a checkpoint inhibitor at study entry, 67% experienced stable disease. Among eight evaluable RCC patients, 75% were progressing and 25% had stable disease at study entry. Stable disease was achieved in 75%, all of whom were progressing on a checkpoint inhibitor at study entry. With 3.7% immune-related adverse events Grade ≥ 3 across the entire study, the data suggest there was no apparent increase in the rate or severity of immune related events compared to historical rates.

A collaboration with Bristol-Myers Squibb was expanded in November 2017 such that subsequent melanoma development costs would be shared, and a joint development committee will be established to guide the development and regulatory strategy of the combination therapy.

Evaluation of CB-839 in Combination with Paclitaxel in Triple Negative Breast Cancer (TNBC)

In July 2017, we initiated CX-839-007, a Phase 2 trial of CB-839 with paclitaxel in TNBC patients. Based on our preliminary Phase 2 clinical trial results and recent changes in the competitive landscape of TNBC, we do not plan to pursue further development of CB-839 plus paclitaxel in triple negative breast cancer patients at this time. We will continue to assess the CB-839 competitive landscape to determine if there is rationale to pursue other combinations in TNBC.

Evaluation of CB-839 in PIK3CA-mutated Colorectal Carcinoma (CRC)

CRC is one of the most common cancers with approximately 140,250 new cases and 50,630 deaths in the U.S. in 2018, according to the American Cancer Society. The oncogene PIK3CA, which encodes the p110 catalytic subunit of phosphatidylinositol-3-kinase , is one of the most frequently mutated oncogenes in human cancers and is common in CRC. Mutations in PIK3CA are found in approximately 10%-20% of CRC, which will result in between 14,000 and 28,000 new cases of mutated PIK3CA CRC in the United States in 2018.

An academic research group at Case Western Reserve University demonstrated that single agent CB-839 inhibits the growth of CRC tumors with PIK3CA mutations in immune-compromised mice, but CRC tumors with a normal PIK3CA gene were not inhibited. Remarkably, the combination of CB-839 with 5-florouracil induced complete and long-lasting tumor regressions in animals bearing PIK3CA mutant CRC tumors, but not tumors with normal PIK3CA, suggesting that this combinational therapy may be a unique and effective approach in the clinic.

An investigator-sponsored clinical trial was initiated by Drs. Jennifer Eads, Alok Khorana, and Neal Meropol, at the Case Western Comprehensive Cancer Center. This research is supported by a Stand Up To Cancer Colorectal Cancer Dream Team Translational Research Grant (Grant Number: SU2C-AACR-DT22-17). The Phase 1 portion of the trial is designed to determine safety and the recommended dose of the combination of CB-839 and capecitabine in patients with advanced treatment refractory solid tumors, while the Phase 2 portion of the trial is designed to evaluate activity of the regimen in patients with late line PIK3CA mutant colorectal cancer. To date, 16 patients have been enrolled, including 12 patients with colorectal cancer. Colorectal patients must have progressed on prior fluoropyrimidine containing therapy. In the dose escalation phase of the trial, there were no dose limiting toxicities and CB-839 plus capecitabine was well tolerated at full dose of CB-839. The recommended Phase 2 dose for the combination is CB-839 at 800 mg BID with capecitabine at 1000 mg/m2 BID. All late-line colorectal cancer patients had progressed on at least one prior fluoropyrimidine-containing regimen. For colorectal patients with PIK3CA mutated cancer (n=7), the median PFS was 26 weeks and for patients with PIK3CA wild-type cancer (n=5) the median PFS was 16 weeks (p=0.058). These results compare favorably to historical data on third line CRC patients receiving standard of care therapies, where the median PFS is approximately 8 weeks. The Phase 2 dose expansion portion of this study in patients with PIK3CA mutant colorectal cancer is ongoing.

Additional Development Opportunities

CB-839 is also the subject of a number of additional investigator-sponsored clinical trials and the National Cancer Institute, or NCI, Cancer Therapy Evaluation Program (CTEP). Investigator sponsored trials are ongoing in RAS wild-type colorectal cancer and myelosdysplastic syndromes and a third trial is planned in IDH mutated astrocytoma. CTEP currently plans to sponsor four additional Phase 1 trials of CB-839 for the treatment of NSCLC, soft tissue sarcoma and glioma. The study designs for the CETP trials are currently being evaluated as project teams are established.

INCB001158

Our product candidate INCB001158, which is a potent and selective orally bioavailable inhibitor of the enzyme arginase, was discovered by us and is being co-developed with Incyte. Arginase depletes arginine, a nutrient that is critical for the activation and proliferation of the body's cancer-fighting immune cells, such as cytotoxic T-cells and natural killer (NK)-cells. During normal activation of the immune system, arginase, which is expressed by suppressive myeloid immune cells, plays an important role in halting T-cell proliferation. But in many tumors, including lung, gastrointestinal, bladder, renal cancer, squamous cell cancer of the head and neck, and acute myeloid leukemia, arginase-expressing myeloid cells accumulate and maintain an immunosuppressive environment, blocking the ability of T-cells and NK-cells to kill cancer cells. We believe that inhibitors of arginase can promote an anti-tumor immune response by restoring arginine levels, thereby allowing activation of the body's own immune cells, including cytotoxic T-cells and NK-cells. INCB001158 is currently being evaluated in Phase 1/2 solid tumor clinical trials. Data from INCB001158 is expected to be presented at a medical meeting in the first half of 2019.

INCB001158 entered clinical trials in September 2016. The first Phase 1/2 trial (NCT02903914) was designed to evaluate the safety of the drug and to determine the recommended Phase 2 dose of INCB001158 as a monotherapy and in combination with immune checkpoint therapy. We presented monotherapy data in June 2017 at the American Society of Clinical Oncology, or ASCO, annual meeting. As of the data cut-off date of April 24, 2017, a total of 17 patients with advanced solid tumors had received single agent doses ranging from 50 to 150 mg twice a day. INCB001158 was generally well-tolerated with no drug-related serious adverse events. Treatment related adverse events were limited to one case each of Grade 1 anemia, fatigue, increased ALT and myalgia. No Grade 3 treatment-related adverse events were reported. Reversible, asymptomatic elevations of urinary orotic acid, a highly sensitive marker of urea cycle inhibition, were observed in two patients at 150 mg BID. At 50 and100 mg, plasma levels of arginase were inhibited continuously at > 90% in all patients, and in 10 of 11 patients plasma arginine increased 1.5-fold or more.

The recommended Phase 2 dose for monotherapy is 100 mg BID and monotherapy expansion cohorts in non-small cell lung cancer, colorectal cancer, and other solid tumors are currently enrolling patients. Expansion cohorts of INCB001158 dosed in combination with Keytruda® are enrolling checkpoint naïve patients diagnosed with metastatic microsatellite stable, or MSS, colorectal cancer, gastric cancer, squamous cell head and neck cancer and mesothelioma. Expansion cohorts of INCB001158 dosed in combination with Keytruda® are also enrolling patients who had prior checkpoint inhibitor therapy as their most immediate prior therapy. These cohorts include patients diagnosed with non-small cell lung cancer, melanoma, urothelial cell carcinoma, and microsatellite instable, or MSI, colorectal cancer. A second clinical trial (NCT03314935) designed to evaluate INCB001158 in combination with chemotherapy opened for enrollment in November 2017. This Phase 1/2 chemotherapy combination trial in patients with solid tumors (including metastatic microsatellite stable, or MSS, colorectal cancer, biliary tract cancer, gastroesophageal cancer, endometrial cancer or ovarian cancer), is evaluating INCB001158 administered twice daily with either folinic acid, fluorouracil and oxaliplatin, also known as FOLFOX, gemcitabine/cisplatin or paclitaxel. Primary endpoints include safety and objective response rate. We believe that INCB001158 is the only arginase inhibitor in clinical trials.

In January 2017, we entered into a collaboration and license agreement, or the Incyte Collaboration Agreement, with Incyte Corporation. Under the terms of the Incyte Collaboration Agreement, we granted Incyte an exclusive, worldwide license to develop and commercialize its small molecule arginase inhibitors for hematology and oncology indications. The parties are collaborating on and co-funding the development of the licensed products, and, unless we opt out of our co-funding obligation, Incyte will fund 70% of global development costs and we will be responsible for the remaining 30%. The parties will share profits and losses in the U.S., with 60% to Incyte and 40% to us. We will have the right to co-detail the licensed products in the U.S, and Incyte will pay us tiered royalties ranging from the low to mid-double digits on net sales of licensed products outside the U.S. We may opt out of our co-funding obligation, in which case the U.S. profit sharing will no longer be in effect, and Incyte will pay us tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the U.S. and outside the U.S., and additional royalties to reimburse us for previously incurred development costs.

CB-280

Under our collaboration agreement with Incyte, we retained the rights to develop a second arginase inhibitor in specific non-oncology rare disease indications, including cystic fibrosis, or CF. We have selected CB-280 to advance into clinical development in cystic fibrosis. We plan to file an investigational new drug, or IND, application for CB-280 with the FDA and initiate a Phase 1 clinical trial in the first half of 2019.

Arginase has been proposed to be critical in the pathophysiology of CF. Reduced arginine is thought to exacerbate pulmonary disease in CF by impairing production of nitric oxide, leading to diminished airway function and a diminished anti-bacterial immune response. Sputum from patients with CF, have elevated arginase activity and diminished levels of arginine. Reduced airway nitric oxide has been observed in the bronchial airways of patients with CF, and correlates directly with worsened lung function and increased colonization with pathogens, including

Pseudomonas aeruginosa. Calithera, along with our pre-clinical collaborators, have validated arginase inhibitors in mouse models of CF. Based on pre-clinical studies in a mouse model of CFTR mutated CF, we believe that arginase inhibition can lead to improvements in lung function and reduction of Pseudomonas aeruginosa infection. We believe these data support the clinical development of CB-280 in CF and we look forward to the presentation of these data in the near future.

Oral Small Molecule Inhibitor of CD73

We have developed a small molecule inhibitor of CD73. CD73 is an enzyme in the adenosine pathway that plays a critical role in converting extracellular ATP into adenosine, a powerful inhibitor of immune cell activity in tumors. CD73 has a soluble form and a cell surface bound form. There are anti-CD73 monoclonal antibodies currently in clinical trials, but we believe that direct inhibition of CD73 with a small molecule may be preferable, as a small molecule that binds directly to the active site of the enzyme could efficiently inhibit both soluble and cell surface forms of CD73 and may be able to more fully inhibit the CD73 enzyme in tumors. We have identified a CD73 inhibitor, CB-708, as a clinical candidate and plan to file an IND and initiate clinical studies in 2019.

Critical Accounting Policies and Estimates

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Revenue from Contracts with Customers (Topic 606), or ASC 606, using the modified retrospective approach. Under this approach, we recorded a cumulative adjustment to decrease accumulated deficit and deferred revenue by $8.8 million. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We have a collaboration and licensing agreement that is within the scope of ASC 606, under which we license certain rights to one of our product candidates to Incyte Corporation. The terms of this arrangement include payment to us of a non-refundable, upfront license fee, and potential development, regulatory and sales milestones, and sales royalties. Each of these payments results in collaboration revenues, except for revenues from royalties on net sales of licensed products, which would be classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreement, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract.

Licenses of Intellectual Property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promised goods or services, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, regulatory or commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensees' control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. The transaction price is then allocated to each performance obligation on a relative stand-alone selling

price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

Contract Balances

Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional.

We receive payments from Incyte based on billing schedules established in the contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

For a discussion of our other significant accounting policies, please see our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Except for our revenue recognition policy, there have been no material changes in our critical accounting policies during the nine months ended September 30, 2018, as compared to those disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" in our Form 10-K dated December 31, 2017, filed with the SEC.

Financial Overview

Collaboration Revenue

Collaboration revenue represents the portion of deferred revenue recognized from a $45.0 million upfront fee and $12.0 million milestone achieved in the first quarter of 2017, both from the Incyte Collaboration Agreement. The combined transaction price of $57.0 million was recognized over the estimated period of performance under the Incyte Collaboration Agreement based on the measure of progress toward completion for the combined performance obligation, which was satisfied as of June 2018. Effective January 1, 2018, we adopted ASC 606 using the modified retrospective approach. Refer to Item 1, Notes to condensed consolidated financial statements, Notes 2 and 9, for further information on the adoption of ASC 606 and the Incyte Collaboration Agreement.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. Costs associated with co-development activities performed under the Incyte Collaboration Agreement and our other collaboration agreement are included in research and development expenses, with any reimbursement of costs by Incyte and our other collaborator reflected as a reduction of such expenses.

Research and development expenses consist primarily of the following:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses incurred under agreements with clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of preclinical studies and clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies;
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation expense and other supplies; and
- license fees and milestone payments related to our licensing agreements.

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The largest component of our total operating expenses has historically been our investment in research and development activities including the clinical development of our product candidates. We allocate to research and development expenses the salaries, benefits, stock-based compensation expense, and indirect costs of our clinical and preclinical programs on a program-specific basis, and we include these costs in the program-specific expenses. The following table shows our research and development expenses for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)			
Development:				
CB-839	$10,669	$7,552	$33,973	$18,578
INCB001158	1,919	1,142	5,139	3,592
CB-280	1,216	—	1,823	—
Total development	13,804	8,694	40,935	22,170
Preclinical and research:				
Preclinical and research	2,616	2,139	8,283	5,445
Total Research and Development	$16,420	$10,833	$49,218	$27,615

We expect our research and development expenses will increase during the next few years as we advance our product candidates into and through clinical trials, and pursue regulatory approval of our product candidates, which will require a significant investment in contract manufacturing and inventory build-up related costs.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses and other expenses for outside professional services, including legal, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation expense and other supplies. We have incurred and expect to continue to incur additional expenses as a result of operating as a public company, including costs to comply with the rules and regulations applicable to companies listed on a national securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC, particularly after we cease to be an “emerging growth company.” In addition, we have incurred and expect to continue to incur increased expenses associated with being a public company, including additional legal, insurance, investor relations and other increases related to needs for additional human resources and professional services.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

	Three Months Ended September 30,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Revenue:				
Collaboration revenue	$—	$7,254	$(7,254)	-100%
Total revenue	—	7,254	(7,254)	-100%
Operating expenses:				
Research and development	16,420	10,833	5,587	52 %
General and administrative	3,087	3,074	13	0 %
Total operating expenses	19,507	13,907	5,600	40 %
Loss from operations	(19,507)	(6,653)	(12,854)	193 %
Interest income, net	658	582	76	13 %
Net loss	$(18,849)	$(6,071)	$(12,778)	210 %

Collaboration Revenue. Collaboration revenue decreased from $7.3 million for the three months ended September 30, 2017 to $0 for the three months ended September 30, 2018, or 100%. The decrease related to the satisfaction of our and Incyte's combined performance obligation under the Incyte Collaboration Agreement, for which revenue recognized in each period was determined based on the measure of progress toward the completion of the manufacturing services and technology transfer to Incyte, which occurred in June of 2018. Refer to Item 1, Notes to condensed consolidated financial statements, Notes 2 and 9, for further information on the adoption of ASC 606 and the Incyte Collaboration Agreement.

Research and Development. Research and development expenses increased $5.6 million, or 52%, from $10.8 million for the three months ended September 30, 2017 to $16.4 million for the three months ended September 30, 2018. The increase of $5.6 million was due to a $3.1 million increase in the CB-839 program to support our new and ongoing clinical trials, including for our Phase 2 CANTATA trial which opened in 2018, an increase of $0.8 million in the INCB001158 program, an increase of $1.2 million in the CB-280 program, and an increase of $0.5 million for investment in our early stage research programs.

General and Administrative. General and administrative expenses were $3.1 million for both the three months ended September 30, 2017 and 2018 due to consistent headcount and stock-based compensation expense.

Interest Income, net. Interest income, net increased $0.1 million, from $0.6 million for the three months ended September 30, 2017 to $0.7 million for the three months ended September 30, 2018. The increase of $0.1 million was due to higher interest income generated from higher returns on our investments, partially offset by lower cash equivalents and investment balances compared to the prior year.

Comparison of the Nine Months Ended September 30, 2018 and 2017

	Nine Months Ended September 30,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Revenue:				
Collaboration revenue	$22,254	$18,701	$3,553	19 %
Total revenue	22,254	18,701	3,553	19 %
Operating expenses:				
Research and development	$49,218	$27,615	$21,603	78 %
General and administrative	10,093	9,230	863	9 %
Total operating expenses	59,311	36,845	22,466	61 %
Loss from operations	(37,057)	(18,144)	(18,913)	104 %
Other income, net	1,927	1,292	635	49 %
Net loss	$(35,130)	$(16,852)	$(18,278)	108 %

Collaboration Revenue. Collaboration revenue increased $3.6 million, or 19%, from $18.7 million for the nine months ended September 30, 2017 to $22.3 million for the nine months ended September 30, 2018. Collaboration revenue represents the portion of deferred revenue from the Incyte Collaboration Agreement recognized in the period. Effective January 1, 2018, we adopted ASC 606 using the modified retrospective approach. The increase of $3.6 million was primarily due the satisfaction of our and Incyte's combined performance obligation under the Incyte Collaboration Agreement, for which revenue recognized in each period was determined based on the measure of progress toward the completion of the manufacturing services and technology transfer to Incyte, partially offset by differences in accounting under the adoption of ASC 606. Refer to Item 1, Notes to condensed consolidated financial statements, Notes 2 and 9, for further information on the adoption of ASC 606 and the Incyte Collaboration

Agreement.

Research and Development. Research and development expenses increased $21.6 million, or 78%, from $27.6 million for the nine months ended September 30, 2017 to $49.2 million for the nine months ended September 30, 2018. The increase of $21.6 million was due to a $15.4 million increase in the CB-839 program to support our new and ongoing clinical trials, including for our Phase 2 CANTATA trial which opened in 2018, an increase of $1.6 million in the INCB001158 program, an increase of $1.8 million in the CB-280 program, including to support our IND application, and an increase of $2.8 million for investment in our early stage research programs.

General and Administrative. General and administrative expenses increased $0.9 million, or 9%, from $9.2 million for the nine months ended September 30, 2017 to $10.1 million for the nine months ended September 30, 2018. The increase of $0.9 million was primarily due to $2.5 million in higher personnel-related costs as a result of higher headcount, salary increases and stock-based compensation expense, partially offset by $1.2 million of lower outside professional services, and $0.3 million lower expenses due to the execution of the sublease agreement for our office and laboratory space in the first quarter of 2017.

Interest Income, net. Interest income, net increased $0.6 million, from $1.3 million for the nine months ended September 30, 2017 to $1.9 million for the nine months ended September 30, 2018. The increase of $0.6 million was due to higher interest income generated from higher returns on our investments, partially offset by lower cash equivalents and investment balances compared to the 2017 period.

Liquidity and Capital Resources

As of September 30, 2018, we had cash, cash equivalents and investments totaling $141.5 million. Our operations have been financed by net proceeds from the sale of shares of our capital stock and payments from the Incyte Collaboration Agreement.

In August 2017, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission which permits the offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our common stock. As of September 30, 2018, $242.5 million of our common stock remained available for sale, of which up to $42.5 million may be issued and sold pursuant to an at-the-market offering program for sales of our common stock under a sales agreement with Cowen and Company, LLC, subject to certain conditions as specified in the sales agreement.

Our primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe that our existing cash, cash equivalents and investments as of September 30, 2018 will be sufficient for us to meet our current operating plan for at least the twelve-month period following the filing of our September 30, 2018 Form 10-Q. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In order to complete the process of obtaining regulatory approval for our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our planned clinical trials for our product candidates;
- the timing and costs of our planned preclinical studies of our product candidates;
- our success in establishing and scaling commercial manufacturing capabilities;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- subject to receipt of regulatory approval, revenue received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
-

- the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights; and
- the extent to which we in-license or acquire other products and technologies.

We plan to continue to fund our operations and capital funding needs through reimbursement of expenses under our existing collaboration agreements and through equity and/or debt financing. We may also consider further collaborations or selectively partnering for clinical development and commercialization. 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. 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.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Cash provided by (used in) operating activities	$(50,954)	$25,114
Cash provided by (used in) investing activities	$57,394	$(117,090)
Cash provided by financing activities	$6,220	$121,180

Cash Flows Provided By (Used In) Operating Activities

Cash used in operating activities for the nine months ended September 30, 2018 was $51.0 million. Our net loss of $35.1 million was offset in part by non-cash charges of $5.6 million of stock-based compensation and $0.3 million for depreciation and amortization. The change in operating assets and liabilities was primarily related to a $22.3 million decrease in deferred revenue related to the Incyte Collaboration Agreement, a $0.7 million increase in the receivable related to our collaboration agreements, and a $1.2 million increase primarily due to the timing of payments for our research and development activities.

Cash provided by operating activities for the nine months ended September 30, 2017 was $25.1 million. Our net loss of $16.9 million was offset in part by non-cash charges of $4.0 million of stock-based compensation and $0.6 million for depreciation and amortization. The change in operating assets and liabilities was primarily related to a $38.3 million increase in deferred revenue and a $1.3 million increase primarily due to the timing of payments for our research and development activities, offset by a $2.2 million increase in the receivable related to the Incyte Collaboration Agreement.

Cash Flows Provided By (Used In) Investing Activities

Cash provided by investing activities was $57.4 million for the nine months ended September 30, 2018 and was related to proceeds from the maturity of investments of $104.9 million, partially offset by the purchases of investments of $47.3 million and property and equipment of $0.2 million.

Cash used in investing activities was $117.1 million for the nine months ended September 30, 2017 and was related to the purchases of investments of $174.3 million, offset by the sale or maturity of investments of $57.9 million and purchase of property and equipment, primarily for leasehold improvements of our office and laboratory space, of $0.7 million.

Cash Flows Provided By Financing Activities

Cash provided by financing activities was $6.2 million for the nine months ended September 30, 2018 and related to $5.6 million in net proceeds from the issuance of common stock under our ATM program and issuance of common stock upon the exercise of stock options and employee stock plan purchases of $0.6 million.

Cash provided by financing activities was $121.2 million for the nine months ended September 30, 2017 and was related to $75.4 million in net proceeds from the sale and issuance of common stock related to our public offering, $7.9 million in net proceeds from the issuance of common stock under our stock purchase agreement with Incyte, $36.9 million in net proceeds from the issuance of common stock through our prior ATM program, and the issuance of common stock upon the exercise of stock options and employee stock plan purchases of $1.0 million.

Contractual Obligations and Other Commitments

There have been no material changes to the contractual obligations during the three months ended September 30, 2018, as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Off-Balance Sheet Arrangements

During 2017 and the nine months ended September 30, 2018, we did not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

Please refer to Note 1 to our unaudited condensed consolidated financial statements appearing under Part I, Item 1 for a discussion of new accounting standards updates that may impact us.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies and highly rated banks and corporations, subject to certain concentration limits. Our investment policy prohibits us from holding auction rate securities or derivative financial instruments. As of September 30, 2018, we had cash, cash equivalents and investments of $141.5 million. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, we believe that our exposure to interest rate risk is not significant as the majority of our investments are short-term in duration and due to the low risk profile of our investments, a 1% change in interest rates would not have a material impact on the total market value of our portfolio. We have the ability to hold our investments until maturity, and therefore we do not expect that our results of operations or cash flows would be adversely affected by any change in market interest rates on our investments. We actively monitor changes in interest rates. We had no outstanding debt as of September 30, 2018.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of September 30, 2018, management, with the participation of our President and Chief Executive Officer (who serves as our principal executive officer and principal financial officer), performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms, and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our President and Chief Executive Officer concluded that, as of September 30, 2018, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the three months ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

Our business involves significant risks, some of which are described below. You should carefully consider the following risk factors, in addition to the other information contained in this report on Form 10-Q, including our financial statements and related notes and the section of this report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations”. The occurrence of any of the events or developments described in the following risk factors and the risks described elsewhere in this report could harm our business, financial condition, results of operations, cash flows, the trading price of our common stock and our growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. 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. The risks relating to our business set forth in our Annual Report on Form 10-K, filed with the SEC, are set forth below and are unchanged substantively as of September 30, 2018, except for those risks designated by an asterisk (*).

Risks Related to Our Financial Position and Need For Additional Capital

We have incurred significant operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or maintain profitability.*

Since our inception, we have incurred significant operating losses. Our net loss was $27.8 million and $35.1 million for year ended December 31, 2017 and the nine months ended September 30, 2018, respectively. As of September 30, 2018, we had an accumulated deficit of $176.7 million. To date, we have financed our operations through sales of our capital stock and payments from the Incyte Collaboration Agreement. We have devoted substantially all of our financial resources and efforts to research and development. We expect that it will be many years, if ever, before we receive regulatory approval and have a product candidate ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance further into clinical trials for our existing clinical product candidates, CB-839 and INCB001158;
- continue the preclinical development of our research programs and advance candidates into clinical trials;
- identify additional product candidates and advance them into preclinical development;
- pursue regulatory approval of product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
-

add operational, financial and management information systems and personnel, including personnel to support product development;

- acquire or in-license other product candidates and technologies; and
- operate as a public company.

We have never generated any revenue from product sales and may never be profitable. To become and remain profitable, we and our collaborators must develop and eventually commercialize one or more products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our

research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of and seek marketing approval for our product candidates, specifically CB-839 and INCB001158, and as we become obligated to make milestone payments pursuant to our outstanding license agreements. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution of the approved product.

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

- the scope, progress, results and costs of drug discovery, clinical development, laboratory testing and clinical trials for our product candidates, in particular CB-839 and INCB001158;
- the costs, timing and outcome of any regulatory review of our product candidates, CB-839 and INCB001158;
- the cost of any other product programs we pursue;
    - the costs and timing of commercialization activities, including manufacturing, marketing, sales and distribution, for any product candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- achieving the milestones set forth in the Incyte Collaboration Agreement;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical studies and clinical trials are time consuming, expensive and uncertain processes that take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales for any of our current or future product candidates. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

We do not have any material committed external source of funds or other support for our development efforts other than the Incyte Collaboration Agreement for the development and commercialization of small molecule arginase inhibitors in hematology and oncology indications, including INCB001158, which agreement is terminable by Incyte for convenience or following our uncured breach. If Incyte terminates our collaboration agreement, we would need to obtain substantial additional sources of funding to develop INCB001158 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 INCB001158 development program or dedicate resources allocated to other programs to fund INCB001158. We may also need to grant rights in the United States, as well as outside the United States, to INCB001158 to one or more partners.

Accordingly, we will need substantial additional funding in connection with our continuing operations and to achieve our goals. We expect that our existing cash, cash equivalents, and investments will be sufficient to enable us to meet our current operating plan for at least the next 12 months. However, our existing cash, cash equivalents and investments may prove to be insufficient for these activities. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional financing due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our operating plans.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings, as well as entering into new collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds, other than our collaborations, which are limited in scope and duration. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted,

and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and may be secured by all or a portion of our assets. If we raise funds by entering into new collaborations, strategic alliances or licensing arrangements in the future with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We were founded in March 2010 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and commencing Phase 1 and 2 clinical trials of our product candidates. CB-839 and INCB001158 are currently being evaluated in Phase 2 and 1/2 clinical trials, respectively. All of our other programs are in research and preclinical development. We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials required for regulatory approval of our product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes many years to develop one new product from the time it is discovered to when it is commercially available. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had product candidates in advanced clinical trials.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors that may alter or delay our plans. We will need to transition from a company with a research focus to a company capable of supporting development activities and, if a product candidate is approved, a company with commercial activities. We may not be successful in any step in such a transition.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected.

Risks Related to Drug Discovery, Development and Commercialization

Our approach to the discovery and development of product candidates that target tumor metabolism and tumor immunology is unproven and may never lead to marketable products.

Our scientific approach focuses on using our understanding of cellular metabolic pathways and the role of glutaminase in these pathways, as well as the role of arginase in the anti-tumor immune response, to identify molecules that are potentially promising as therapies for cancer indications. Any product candidates we develop may not effectively modulate metabolic or immunology pathways. The scientific evidence to support the feasibility of developing product candidates based on inhibiting tumor metabolism or impacting the anti-tumor immune response are both preliminary

and limited. Although preclinical studies suggest that inhibiting glutaminase can suppress the growth of certain cancer cells, to date no company has translated this mechanism into a drug that has received marketing approval. Even if we are able to develop a product candidate in preclinical studies, we may not succeed in demonstrating the safety and efficacy of the product candidate in human clinical trials. Our expertise in cellular metabolic pathways, the role of glutaminase in these pathways, and the role of arginase in the anti-tumor immune response may not result in the discovery and development of commercially viable products to treat cancer.

We are very early in our development efforts, which may not be successful.*

We have invested a significant portion of our efforts and financial resources in the identification of our most advanced product candidates, CB-839 and INCB001158, which are being evaluated in Phase 2 and Phase 1/2 clinical trials, respectively. We have entered into the Incyte Collaboration Agreement for the development and commercialization of INCB001158. Pursuant to our agreement, we collaborate on and co-fund the development of INCB001158 for hematology and oncology indications, and, unless we opt out of our co-funding obligation, Incyte will fund 70% of global development costs and we will be responsible for the remaining 30%. All of our other programs are in research and preclinical development. It is also too early in our development efforts to determine whether our product candidates will demonstrate single-agent activity or will be developed for use in combination with other approved therapies, or both. As a result, the timing and costs of the regulatory paths we will follow and marketing approvals remain uncertain. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of CB-839 and INCB001158. The success of CB-839, INCB001158 and any other product candidates we may develop will depend on many factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates;
- launching commercial sales of the product candidates, if and when approved, whether alone or selectively in collaboration with others;
- our ability to successfully develop and commercialize small molecule arginase inhibitors, including INCB001158 with Incyte;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval;
- enforcing and defending intellectual property rights and claims; and
- other legal, regulatory, compliance and fraud and abuse matters.

If we do not accomplish one or more of these goals 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.

We may not be successful in our efforts to identify or discover potential product candidates.

Our drug discovery efforts may not be successful in identifying compounds that are useful in treating cancer. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons. In particular, our research methodology used may not be successful in identifying compounds with sufficient potency or bioavailability to be potential product candidates. In addition, our potential product candidates may, on further study, be shown to have harmful side effects or other negative characteristics.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on potential product candidates that ultimately prove to be unsuccessful. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to generate product revenue, which would harm our financial position and adversely impact our stock price.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities 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 marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and in the case of INCB001158, together with Incyte, then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials could occur at any stage of testing. 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 particular clinical trial do not necessarily predict final results of that trial.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, preclinical testing or clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we 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 anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; 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 are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing 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 may have the

exclusive right to commercialize our product candidates, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the U.S. Food and Drug Administration, or the FDA, or analogous regulatory authorities outside the United States. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of health care professionals;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse effects or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit our development of some or all of our product candidates.

We are currently evaluating CB-839 and INCB001158 in Phase 2 and Phase 1/2 clinical trials, respectively. All our other programs are in research and preclinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. Adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, any current or future collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If adverse effects were to arise in patients being treated with any of our product candidates, it could require us to halt, delay or interrupt clinical trials of such product candidate or adversely affect our ability to obtain requisite approvals to advance the development and commercialization of such product candidate. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many agents that initially showed promise in early stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further development of the agent.

We are in early clinical trials with CB-839 and INCB001158 and we have seen several adverse events, or AEs, deemed possibly or probably related to study drug in each of those programs. For example, in the CB-839-001 study, treatment-emergent Grade ≥ 3 AEs occurring in >5% of patients included increases in liver enzymes aspartate aminotransferase, or AST, and alanine aminotransferase, or ALT. With a change to twice daily dosing with food, only one out of the 66 patients showed a Grade 3 liver enzyme increase. We have treated an insufficient number of patients to fully assess the safety of CB-839 and INCB001158 and, as these trials progress, we may experience frequent or severe adverse events. Our ongoing and planned trials for CB-839 and our and Incyte's ongoing and planned trials for INCB001158 may fail due to safety issues, and we may need to abandon development of CB-839 or INCB001158. Our other research programs may fail due to preclinical or clinical safety issues, causing us to abandon or delay the

development of a product candidate from these programs.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may

experience delays in designing and executing clinical trials to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or our current and future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

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

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that 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 indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements, including our agreement with Incyte, in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, under our agreement with Incyte, Incyte has the right to commercialize INCB001158 in hematology and oncology indications. If Incyte does not successfully commercialize INCB001158, we may be unable to realize the full value from our collaboration with Incyte.

Even if any of our product candidates receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability, or that of any future collaborators, to market the product.

Clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any future collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;

- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by health care professionals, patients, third party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by health care professionals, patients, third party payors and others in the medical community for us to achieve commercial success. For example, current cancer treatments like chemotherapy and radiation therapy for certain diseases and conditions are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue to become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer any approved products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of health care professionals to prescribe these therapies;
- the strength of marketing and distribution support;
- third-party coverage and sufficient reimbursement; and
- the prevalence and severity of any side effects.

If, in the future, we are unable to establish sales and marketing capabilities or to selectively enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties. For our small molecule arginase inhibitors in hematology and oncology indications, including INCB001158, unless we establish our own sales and marketing capabilities, we will be significantly dependent on Incyte's sales and marketing infrastructure to effectively commercialize these products. In the future, we may choose to build a focused sales and marketing infrastructure to sell some of our product candidates if and when they are approved.

There are risks involved both with establishing our own sales and marketing capabilities and with 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 candidate 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 cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to health care professionals or persuade adequate numbers of health care professionals to prescribe any future products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us may be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in 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 may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to

sell and market our products effectively. If we 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.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.*

The development and commercialization of new drug products is highly competitive. Research and discoveries by others may result in breakthroughs which may render our products obsolete even before they generate any revenue. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the cancer indications for which we are focusing our product development efforts. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our product candidates for the treatment of various cancers. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well-established therapies and are widely accepted by health care professionals, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

There are also a number of product candidates in preclinical and clinical development by third parties to treat cancer by targeting cellular metabolism. Our principal competitors in the fields of tumor immunology and/or tumor metabolism include Agios Pharmaceuticals, Inc., Arcus Biosciences, Inc., AstraZeneca plc, Boehringer Ingelheim GmbH, Bayer Pharma AG, Bristol-Myers Squibb Company, Celgene Corporation, Corvus Pharmaceuticals, Inc., CureTech Ltd., Dynavax Technologies Corp., Eisai Co., Ltd., Eli Lilly and Company, Forma Therapeutics Holdings, LLC, GlaxoSmithKline plc, Idera Pharmaceuticals, Inc., Immunomedics Inc., Incyte Corporation, iTeos Therapeutics SA, Merck & Co., Merck KGaA, Nektar Therapeutics, NewLink Genetics Corporation, Novartis International AG, Ono Pharmaceuticals Co., Ltd, Pfizer Inc, Roche Holdings AG and its subsidiary Genentech, Inc., Sprint Bioscience AB, Takeda Pharmaceutical Co., Ltd, and TG Therapeutics, Inc.

Our primary competitors in the field of Cystic Fibrosis include AbbVie, Inc., AIT Therapeutics, Inc., Corbus Pharmaceuticals, Inc., Flatley Discovery Lab, LLC, Galapagos NV, Novartis AG, Novoteris, LLC, Proteostatis Therapeutics, Inc., ProQR Therapeutics NV, Translate Bio, Inc., and Vertex Pharmaceuticals, Inc.

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. In addition, our competitors may discover biomarkers that more efficiently measure metabolic pathways than our methods, which may give them a competitive advantage in developing potential products. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products sooner than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties may compete with us in recruiting and retaining qualified scientific and management

personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, new and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug 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 marketing approval is granted. As a result, we might obtain marketing approval for a drug in a particular country, but then be subject to price regulations that delay its commercial launch, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to commercialize and generate revenue from one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health programs, 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. A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used, may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs 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 drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

In addition, there has been heightened governmental scrutiny of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. We continue to monitor and evaluate the potential impact of these legislative actions and their effect on our business and operations.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any product candidates 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 after approval. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

Although we maintain product liability insurance coverage in the amount of up to $10.0 million per claim and in the aggregate, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. 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.

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 and radioactive 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 in our workplace, including those 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, chemical, hazardous or radioactive materials.

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

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing and manufacture our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as our collaborators, contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time. 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, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, and that all clinical trial activities conducted by our contract research organizations follow applicable laws and regulations, and are conducted in an ethical and compliant manner. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, 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 trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government sponsored database, available at www.clinicaltrials.gov, within certain timeframes. Failure by us, or any of the third parties working on our behalf, to do the above can result in fines, adverse publicity and civil and criminal sanctions.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third party manufacturers for the manufacture of our product candidates for preclinical studies and clinical trials and for commercial supply of any of these product candidates for which we obtain marketing approval. To date, we have obtained or plan to obtain materials for CB-839 and INCB001158 for our current and planned clinical trials from third-party manufacturers. We have engaged third party manufacturers to obtain the active ingredient for CB-839 and INCB001158 for pre-clinical testing and clinical trials. We do not have a long-term supply agreement with any third-party manufacturers, and we purchase our required drug supply on a purchase order basis.

We may be unable to establish agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for legal and regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current U.S. Good Manufacturing Practice requirements, or cGMPs, or similar legal and regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations.

Any product that we may develop may compete with other product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We also currently rely, and expect to continue to rely, on third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our drugs, producing additional losses and depriving us of potential revenue. Although we believe that there are several potential alternative third parties who could store and distribute drug supplies for our clinical trials, we may incur added costs and delays in identifying and qualifying any such replacement.

Our arginase inhibitors program in hematology and oncology indications, including INCB001158, is reliant in part on Incyte for the successful development and commercialization in a timely manner. If Incyte does not devote sufficient resources to INCB001158's development, is unsuccessful in its efforts, or chooses to terminate its agreement with us, our business, operating results and financial condition will be harmed.

We have entered into the Incyte Collaboration Agreement under which we have granted Incyte an exclusive, worldwide license to develop and commercialize small molecule arginase inhibitors for hematology and oncology indications, including INCB001158, which is currently in Phase 1/2 clinical trials.

Under the agreement, we and Incyte will jointly conduct and co-fund development of INCB001158, with Incyte leading global development activities. Unless we opt out of our co-funding obligation, Incyte will fund 70% of global development costs and we will be responsible for the remaining 30%. Should we disagree with Incyte about the clinical development or commercialization strategy, we could escalate the disagreement to our representatives on the Joint Steering Committee for resolution. We and Incyte are obligated to use good faith efforts to resolve such disputes; however, in cases of deadlock, Incyte will have the deciding vote. If the agreement is terminated, other than as a result of our breach, with respect to one or more products or countries, all rights in the terminated products and countries revert to us. The Incyte 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, including diligence obligations, although Incyte has certain obligations to use commercially reasonable efforts to develop and commercialize INCB001158, Incyte has 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 INCB001158;

- Incyte may select a dose for INCB001158 that does not have a favorable benefit/risk profile;
- Incyte 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;
- Incyte may develop or commercialize INCB001158 in a way that exposes us to potential litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability; and

If Incyte 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 Incyte due to Incyte's breach or if Incyte were to terminate the agreement without cause, there could be a delay in the return of our rights to INCB001158 and the development and commercialization of INCB001158 would be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization on our own.

Incyte 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 Incyte's ability to retain and motivate key personnel who are important to the continued development of the small molecule arginase inhibitor program. In addition, the third party to any such transaction could reprioritize Incyte's development programs which could delay the development of our programs or cause Incyte to terminate the agreement.

We have in the past and may seek in the future to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. In addition to our collaboration with Incyte, for some of our product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We may also be restricted under existing license agreements from engaging in research and development activities or entering into future agreements on certain terms with potential collaborators. For example, pursuant to our license agreement with Symbioscience, we have agreed not to develop any other arginase inhibitors for use in human healthcare outside of the scope of that agreement. In addition, under our agreement with Incyte, we are not allowed to develop any retained arginase inhibitors (small molecule arginase inhibitors, other than INCB001158, retained by us for research and development in non-hematology/oncology indications) for any indication except specific orphan indications outside of hematology and oncology.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we decide to collaborate with any other third parties in connection with any of our development programs or product candidates, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development program or the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our

expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

To the extent we enter into any other collaborations, we may depend on such collaborations for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

We may selectively seek additional third-party collaborators for the development and commercialization of our product candidates. Our current and any future collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Pursuant to these arrangements and any potential future arrangements, 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 revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates, including our collaboration with Incyte, pose many risks to us, including that:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these 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 the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or products if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- A collaborator with marketing and distribution rights to one or more product candidates or products may not commit sufficient resources to the marketing and distribution of such drugs;
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or products or that result in costly litigation or arbitration that diverts management attention and resources;
- We may lose certain valuable rights under circumstances identified in our collaborations if we undergo a change of control;
- 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
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

We have in-licensed a portfolio of arginase inhibitors as part of our efforts to develop product candidates for the arginase program, and we are substantially dependent on this in-license for that program. To the extent this in-license is terminated, our business may be harmed.

Our internal computer systems, or those used by our Clinical Research Organizations or other contractors or consultants, may fail or suffer security breaches.*

Despite the implementation of security measures, our internal computer systems, and those of our Clinical Research Organizations and other third parties on which we rely, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could

also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

Risks Related to Our Intellectual Property

Recent laws and rulings by U.S. courts make it difficult to predict how patents will be issued or enforced in our industry.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. There have been numerous recent changes to the patent laws and to the rules of the United States Patent and Trademark Office, or the USPTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the Leahy-Smith America Invents Act, which was signed into law in 2011, includes a transition from a "first-to-invent" system to a "first-to-file" system, and changes the way issued patents are challenged. Certain changes, such as the institution of inter partes review proceedings, came into effect on September 16, 2012. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and, if obtained, to enforce or defend them in litigation or post-grant proceedings, all of which could harm our business.

Furthermore, the patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Two cases involving diagnostic method claims and "gene patents" have recently been decided by the Supreme Court. On March 20, 2012, the Supreme Court issued a decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., or Prometheus, a case involving patent claims directed to measuring a metabolic product in a patient to optimize a drug dosage amount for the patient. According to the Supreme Court, the addition of well-understood, routine or conventional activity such as "administering" or "determining" steps was not enough to transform an otherwise patent ineligible natural phenomenon into patent eligible subject matter. On July 3, 2012, the USPTO issued guidance indicating that process claims directed to a law of nature, a natural phenomenon or an abstract idea that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to non-statutory subject matter. On June 13, 2013, the Supreme Court issued its decision in Association for Molecular Pathology v. Myriad Genetics, Inc., or Myriad, a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2. Myriad held that isolated segments of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent eligible.

We cannot assure you that our efforts to seek patent protection for our technology and products will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact the Supreme Court's decisions in Prometheus and Myriad may have on the ability of life science companies to obtain or enforce patents relating to their products and technologies in the future.

Moreover, although the Supreme Court has held in Myriad that isolated segments of naturally occurring DNA are not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other gene-related patent claims, and we may deem it necessary to defend ourselves against these claims by asserting non-infringement and/or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter. Such outcomes could harm our business.

If we are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities may be alleged to infringe patents, trademarks or other intellectual property rights owned by other parties. Certain of our competitors and other companies in the industry

have substantial patent portfolios and may attempt to use patent litigation as a means to obtain a competitive advantage. We may be a target for such litigation. Even if our pending patent applications issue, they may relate to our competitors' activities and may therefore not deter litigation against us. The risks of being involved in such litigation may also increase as we become more visible as a public company and move into new markets and applications for our product candidates. There may also be patents and patent applications that are relevant to our technologies or product candidates that are unknown to us. For example, certain relevant patent applications may have been filed but not published. If such patents exist, or if a patent issues on any of such patent applications, that patent could be asserted against us. Third parties could bring claims against us that would cause us to incur substantial expenses and, if the claims against us are successful, could cause us to pay substantial damages, including treble damages and attorneys' fees for willful infringement. The defense of such a suit could also divert the attention of our management and technical personnel. Further, if an intellectual property infringement suit were brought against us, we could be forced to stop or delay research, development or sales of the product that is the subject of the suit.

As a result of infringement claims, or to avoid potential claims, we may choose or be compelled to seek intellectual property licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us likely would be nonexclusive, which would mean that our competitors also could obtain licenses to the same intellectual property. Ultimately, we could be prevented from commercializing a product candidate and/or technology or be forced to cease some aspect of our business operations if, as a result of actual or threatened infringement claims, we are unable to enter into licenses of the relevant intellectual property on acceptable terms. Further, if we attempt to modify a product candidate and/or technology or to develop alternative methods or products in response to infringement claims or to avoid potential claims, we could incur substantial costs, encounter delays in product introductions or interruptions in sales.

We may become involved in other lawsuits to protect or enforce our patents or other intellectual property, which could be expensive and time-consuming, and an unfavorable outcome could harm our business.

In addition to the possibility of litigation relating to infringement claims asserted against us, we may become a party to other patent litigation and other proceedings, including inter partes review proceedings, post-grant review proceedings, derivation proceedings declared by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future technologies or product candidates or products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Competitors may infringe or otherwise violate our intellectual property, including patents that may issue to or be licensed by us. As a result, we may be required to file claims in an effort to stop third-party infringement or unauthorized use. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. This can be expensive, particularly for a company of our size, and time-consuming, and even if we are successful, any award of monetary damages or other remedy we may receive may not be commercially valuable. In addition, in an infringement proceeding, a court may decide that our asserted intellectual property is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our intellectual property does not cover its technology. An adverse determination in any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

If the breadth or strength of our patent or other intellectual property rights is compromised or threatened, it could allow third parties to commercialize our technology or products or result in our inability to commercialize our technology and products without infringing third-party intellectual property rights. Further, third parties may be dissuaded from collaborating with us.

Interference or derivation proceedings brought by the USPTO or its foreign counterparts may be necessary to determine the priority of inventions with respect to our patent applications, and we may also become involved in other proceedings, such as re-examination proceedings, before the USPTO or its foreign counterparts. Due to the substantial competition in the pharmaceutical space, the number of such proceedings may increase. This could delay the prosecution of our pending patent applications or impact the validity and enforceability of any future patents that we may obtain. In addition, any such litigation, submission or proceeding may be resolved adversely to us and, even if successful, may result in substantial costs and distraction to our management.

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. Moreover, intellectual property law relating to the fields in which we operate is still evolving and,

consequently, patent and other intellectual property positions in our industry are subject to change and are often uncertain. We may not prevail in any of these suits or other efforts to protect our technology, and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of this type of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We may not be able to protect our intellectual property rights throughout the world, which could impair our competitive position.

Filing, prosecuting, defending and enforcing patents on all of our technologies, product candidates and products throughout the world would be prohibitively expensive. As a result, we seek to protect our proprietary position by filing patent applications in the United States and in select foreign jurisdictions and cannot guarantee that we will obtain the patent protection necessary to protect our competitive position in all major markets. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export infringing products to territories where we may obtain patent protection but where enforcement is not as strong as that in the United States. These products may compete with our current and future products in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. The legal systems of certain countries make it difficult or impossible to obtain patent protection for pharmaceutical products and services. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business.

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

In addition to seeking patents for some of our technologies and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. As a result, we may be forced to bring claims against third parties, or defend claims that they bring against us, to determine ownership of what we regard as our intellectual property. Monitoring unauthorized disclosure is difficult and we do not know whether the procedures we have followed to prevent such disclosure are, or will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States may be less willing or unwilling to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

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

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may refuse to stop the other party from using the trademark at issue. We may not be able to protect our rights to these and other trademarks and trade names which we need to build name recognition by potential partners or customers in our markets of interest. We do not currently have any registered trademarks in the United States. Any trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. In addition, other companies in the biopharmaceutical space may be using trademarks that are similar to ours and may in the future allege that our use of the trademark infringes or otherwise violates their trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be harmed.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our collaborations, or if disputes otherwise arise with respect to the intellectual property developed in the course of a collaboration, we may be limited in our ability to capitalize on the market potential of these inventions.

In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or are in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we or our collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of a product candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to health care professionals and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to

enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling, marketing, distribution or use of a product;
- requirements to conduct post-approval clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;

- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

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

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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 and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the Physician Payments Sunshine Act 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; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. If any of the health care professionals or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.*

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, enacted in 2010, made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. In the years since its enactment, there have been, and continue to be, significant developments in, and continued legislative activity around, attempts to repeal or repeal and replace the PPACA. Due to these efforts, there is significant uncertainty regarding the future of the PPACA.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the PPACA, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the PPACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the PPACA. Any repeal and replace legislation may have the effect of limiting the amounts that government agencies will pay for healthcare products and services. Due to these efforts, there is significant uncertainty regarding the future of the PPACA.

Policy changes, including potential modification or repeal of all or parts of the PPACA or the implementation of new health care legislation could result in significant changes to the health care system, which may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for our product candidates, or additional pricing pressures.

Further, there has been heightened governmental scrutiny of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect that healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of any of our product candidates that we

successfully commercialize.

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

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent upon our senior management team, as well as the other principal members of our research and development teams. All of our executive officers are employed “at will,” meaning we or they may terminate the employment relationship at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be 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. 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 employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our operations, and may encounter difficulties in managing our growth, which could disrupt our business.

We expect to expand the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected expansion of our operations may lead to significant costs and may divert our management and business development resources. For example, our facilities expenses may increase, or decrease which will vary depending on the time and terms of any facility lease or sublease we may enter into from time to time. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. Because we have not made any acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may fail to strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business in various jurisdictions globally.*

Our business strategy incorporates international expansion, including establishing and maintaining relationships with service providers, distributors and manufacturers globally. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- financial risks, such as difficulty enforcing contracts exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- reduced protection of contractual rights in the event of bankruptcy or insolvency of the other contracting party;

- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- failure to comply with foreign laws, regulations, standards and regulatory guidance governing the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Privacy Regulation, or GDPR, which introduces strict requirements for processing personal data of individuals within the European Union; and
- failure to comply with the United Kingdom Bribery Act 2010, or UK Bribery Act, and similar antibribery and anticorruption laws in other jurisdictions, and the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, including by failing to maintain accurate information and control over sales and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international operations and, consequently, negatively impact our financial condition, results of operations and cash flows.

Risks Related to Our Common Stock

The trading price of our common stock is likely to 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 success of competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' product and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual and anticipated fluctuations in our quarterly operating results;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional products or product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, in the past, stockholders have initiated class action lawsuits against companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

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Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own a significant percentage of our outstanding common stock. These persons, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our operating results.

As a public company listed in the United States, we have and will continue to incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the Securities and Exchange Commission, or SEC, and the Nasdaq Global Select Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Further, failure to comply with these laws, regulations and standards might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, on committees of our Board of Directors or as members of senior management.

We do not anticipate paying any cash dividends on our common stock so any returns will be limited to changes in the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future credit facility may restrict our ability to pay dividends. Any return to stockholders will therefore be limited to the increase, if any, of our stock price.

We are an “emerging growth company,” and we expect to comply with the reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012, and for as long as we continue to be an “emerging growth company,” we expect to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, 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 shareholder approval of any golden parachute payments not previously approved. We will continue to be an “emerging growth company” until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering in October 2014, (b) in which we have total annual gross revenue of at least $1.07 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 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive by our reliance on these exemptions. If some investors find our common stock less attractive as a result of our choices to reduce disclosure, there may be a less active trading market for our common stock, and our stock price may be more volatile.

If we are unable to maintain proper and effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected.

Effective internal controls are necessary for us to provide reliable financial reports and to protect from fraudulent, illegal or unauthorized transactions. If we cannot provide effective controls and reliable financial reports, our business and operating results could be harmed. We have in the past discovered, and may in the future discover, areas of our internal controls that need improvement. We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until the earlier of the fifth anniversary of the closing of our initial public offering in October 2014 or until we are no longer an "emerging growth company."

If material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by our stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, such as:

- establishing a classified Board of Directors so that not all members of our Board of Directors are elected at one time;
- permitting the Board of Directors to establish the number of directors and fill any vacancies and newly created directorships;
- providing that directors may only be removed for cause;
- prohibits cumulative voting for directors;
- requiring super-majority voting to amend some provisions in our certificate of incorporation and bylaws;
- authorizing the issuance of "blank check" preferred stock that our Board of Directors could use to implement a stockholder rights plan;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- prohibiting stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibit a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision in our certificate of incorporation or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Calithera Biosciences, Inc.	8-K	001-36644	3.1	10/07/2014
3.2	Amended and Restated Bylaws of Calithera Biosciences, Inc.	S-1	333-198355	3.4	9/19/2014
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of common stock certificate.	S-1	333-198355	4.1	9/25/2014
31.1	Certification of Principal Executive and Financial Officer pursuant to Rule 13a-14(a).				
32.1*	Certification of Principal Executive and 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.				

* The Certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Calithera Biosciences, 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 September 30, 2018 formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Loss, (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.

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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.

Calithera Biosciences, Inc.

Date: November 7, 2018 By: /s/ Susan M. Molineaux
Susan M. Molineaux, Ph.D.
President and Chief Executive Officer
(Principal Executive and Principal Financial Officer)

Date: November 7, 2018 By: /s/ Stephanie Wong
Stephanie Wong
Senior Vice President, Finance and Secretary
(Principal Accounting Officer)