Calithera Biosciences, Inc.
Form 10-Q
August 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2016

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

As of August 4, 2016, the registrant had 19,489,541 shares of common stock, $0.0001 par value per share, outstanding.

Calithera Biosciences, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended June 30, 2016

INDEX

2

PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements

Calithera Biosciences, Inc.

Condensed Balance Sheets

(Unaudited)

(In thousands, except per share amounts)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$7,326	$6,105
Short-term investments	53,054	63,823
Prepaid expenses and other current assets	1,915	2,567
Total current assets	62,295	72,495
Long-term investments	-	1,997
Restricted cash	46	46
Property and equipment, net	854	931
Other assets	34	281
Total assets	$63,229	$75,750
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,446	$562
Accrued liabilities	3,248	3,271
Total current liabilities	4,694	3,833
Deferred rent	316	129
Total liabilities	5,010	3,962
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value, 200,000 shares authorized as of June 30, 2016 and December 31, 2015; 19,014 and 18,232 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	2	2
Additional paid-in capital	162,637	156,353
Accumulated deficit	(104,438)	(84,498)
Accumulated other comprehensive gain (loss)	18	(69)
Total stockholders' equity	58,219	71,788
Total liabilities and stock and stockholders' equity	$63,229	$75,750

See accompanying notes.

Calithera Biosciences, Inc.

Condensed Statements of Operations

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$7,776	$5,533	$14,842	$11,163
General and administrative	2,665	2,341	5,256	4,578
Total operating expenses	10,441	7,874	20,098	15,741
Loss from operations	(10,441)	(7,874)	(20,098)	(15,741)
Interest income, net	83	56	158	65
Net loss	$(10,358)	$(7,818)	$(19,940)	$(15,676)
Net loss per share, basic and diluted	$(0.55)	$(0.44)	$(1.07)	$(0.87)
Weighted average common shares used to compute net loss per share, basic and diluted	18,987	17,963	18,688	17,955

See accompanying notes.

Calithera Biosciences, Inc.

Condensed Statements of Comprehensive Loss

(Unaudited)

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	$(10,358)	$(7,818)	$(19,940)	$(15,676)
Other comprehensive loss:				
Net unrealized gain (loss) on available-for-sale securities	14	(35)	87	(41)
Total comprehensive loss	$(10,344)	$(7,853)	$(19,853)	(15,717)

See accompanying notes.

Calithera Biosciences, Inc.

Condensed Statements of Cash Flows

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2016	2015
Cash Flows From Operating Activities		
Net loss	$(19,940)	$(15,676)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	152	228
Amortization of premiums on investments	343	112
Stock-based compensation	2,114	1,384
Gain on disposal of property and equipment	-	(8)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	618	194
Other assets	281	-
Accounts payable	884	230
Accrued liabilities	254	(21)
Deferred rent, non-current	46	(70)
Net cash used in operating activities	(15,248)	(13,627)
Cash Flows From Investing Activities		
Purchases of investments	(24,060)	(81,557)
Proceeds from sale or maturity of investments	36,570	4,536
Purchase of property and equipment	(211)	(285)
Net cash provided by (used in) investing activities	12,299	(77,306)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock through an at-the-market offering, net	3,971	-
Proceeds from stock option exercises and employee stock plan purchases	199	283
Net cash provided by financing activities	4,170	283
Net increase (decrease) in cash and cash equivalents	1,221	(90,650)
Cash and cash equivalents at beginning of period	6,105	101,969
Cash and cash equivalents at end of period	$7,326	$11,319

See accompanying notes.

6

Calithera Biosciences, Inc.

Notes to Condensed Financial Statements

1. Organization and Basis of Presentation

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 novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. The Company's principal operations are based in South San Francisco, California, and it operates in one segment.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The interim condensed balance sheet as of June 30, 2016, and the statements of operations, comprehensive loss, and cash flows for the six months ended June 30, 2016 and 2015 are unaudited. The unaudited interim 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 financial statements included in this report. The financial data and the other information disclosed in these notes to the financial statements related to the six-month periods are also unaudited. The results of operations for the six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other future annual or interim period. The balance sheet as of December 31, 2015 included herein was derived from the audited financial statements as of that date. These 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 financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the 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 preclinical, clinical trial and contract manufacturing accrued liabilities, fair value of common stock, 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.

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 net loss 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 in the statement of operations. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in interest income, net.

Concentration 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.

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 include these costs in accrued liabilities in the balance sheets and within research and development expense in the 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, 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.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the "FASB"), issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for the Company for the 2016 annual period and with early adoption permitted. The Company will include the required disclosures in our December 31, 2016 annual financial statements to the extent that they are applicable.

In February 2016, the FASB issued ASU 2016-02, Leases. The ASU requires management to recognize lease assets and lease liabilities by lessees for all operating leases. The ASU is effective for the annual period beginning after December 15, 2018 and interim periods therein on a modified retrospective basis. The Company is currently assessing the impact the adoption of ASU 2016-02 will have on its financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation – Stock Compensation. ASU 2016-09 simplified certain aspects of the accounting for share-based payment transactions, including income taxes, classification of awards and classification in the statement of cash flows. ASU 2016-09 is effective for the annual period beginning after December 15, 2016, and interim periods therein. The Company is currently assessing the impact of adopting ASU 2016-09 will have on its financial statements.

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 financial statements on a recurring basis (at least annually). Financial instruments include cash and cash

equivalents, short-term investments, accounts payable and accrued liabilities 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):

	June 30, 2016			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$5,516	$-	$ -	$5,516
Corporate notes and commercial paper	-	23,921	-	23,921
U.S. treasury securities	-	3,019	-	3,019
U.S. government agency securities	-	27,614	-	27,614
Total financial assets	$5,516	$54,554	$ -	$60,070

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$5,548	$-	$ -	$5,548
Corporate notes and commercial paper	-	23,151	-	23,151
U.S. treasury securities	-	4,329	-	4,329
U.S. government agency securities	-	38,340	-	38,340
Total financial assets	$5,548	$65,820	$ -	$71,368

4. Financial Instruments

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

	June 30, 2016				December 31, 2015			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value

Money market funds	$5,516	$ -	$ -	5,516	$5,548	$ -	$ -	5,548
Corporate notes and commercial paper	23,917	6	(2)	23,921	23,186	-	(35)	23,151
U.S. treasury securities	3,015	4	-	3,019	4,334	-	(5)	4,329
U.S. government agency securities	27,604	11	(1)	27,614	38,369	-	(29)	38,340
	$60,052	$ 21	$ (3)	$60,070	$71,437	$ -	$ (69)	$71,368
Classified as:								
Cash equivalents				$6,970				$5,502
Short-term investments				53,054				63,823
Long-term investments				-				1,997
Restricted cash				46				46
Total				$60,070				$71,368

At June 30, 2016, 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 June 30, 2016, the Company had a total of $60.4 million in cash, cash equivalents, and investments, which includes $0.4 million in cash and $60.0 million in cash equivalents and investments.

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2016	December 31, 2015
Accrued bonus and payroll expenses	$1,334	$ 1,696
Accrued professional and consulting services	195	153
Accrued clinical and manufacturing expenses	1,434	921
Accrued preclinical and research expenses	137	194
Other	148	307
Total accrued liabilities	$3,248	$ 3,271

6. Stockholders' Equity

At-the-Market Offering

In November 2015, the Company entered into a sales agreement with Cowen and Company LLC ("Cowen"), as sales agent and underwriter, pursuant to which the Company may issue and sell shares of its common stock for an aggregate maximum offering price of $50.0 million under an at-the-market ("ATM") offering program. The Company will pay Cowen up to 3% of gross proceeds for any common stock sold through the sales agreement.

During the six months ended June 30, 2016, the Company sold an aggregate of 715,383 shares of common stock pursuant to the ATM program, at an average price of approximately $6.21 per share for gross proceeds of $4.4 million, resulting in net proceeds of $4.0 million after deducting underwriting fees and offering expenses. As of June 30, 2016, $45.6 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	Weighted-Average Exercise	Weighted-Average Remaining	Aggregate Value Intrinsic

	Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding — December 31, 2015	1,665	$ 8.80		$ 3,831
Options granted	935	$ 4.78		
Options exercised	(17)	$ 1.03		
Options canceled	(46)	$ 6.74		
Outstanding — June 30, 2016	2,537	$ 7.41	8.57	$ 947

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$479	$354	$916	$624
General and administrative	608	435	1,198	760
Total stock-based compensation	$1,087	$789	$2,114	$1,384

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 per share attributable to common stockholders calculations because they would be anti-dilutive were as follows (in thousands):

	June 30,	
	2016	2015
Options to purchase common stock	2,537	1,872
Total	2,537	1,872

9. Licensing Agreements

Symbioscience License Agreement

In December 2014, the Company entered into an exclusive license agreement with Mars, Inc., by and through its Mars Symbioscience division, or 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"). Under the terms of the Symbioscience License Agreement, the Company paid Symbioscience an upfront license fee of $0.3 million in 2014 which was recorded in research and development expenses in the statement of operations. For the six months ended June 30, 2016 and 2015, the Company made milestone payments of $0.2 million and $0.2 million, respectively, which were recorded in research and development expenses in the statement of operations. No payments were made for the three months ended June 30, 2016 and 2015.

The Company may make future payments of up to $24.0 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.

vTv License Agreement

In March 2015, the Company entered into a License and Research agreement with High Point Pharmaceuticals, LLC and TransTech Pharma LLC, or collectively TransTech, under which the Company obtained an exclusive, worldwide license to develop and commercialize TransTech's hexokinase II inhibitors ("vTv License Agreement"). The agreement was subsequently assigned by TransTech to its parent company, vTv Therapeutics LLC ("vTv"). Under the terms of the vTv License Agreement, the Company paid an initial license fee of $0.6 million in 2015, which was recorded in research and development expense in the statement of operations. For the three and six months ended June 30, 2015, the Company recognized expense of $0 million and $0.6 million, respectively, which was recorded in research and development expense in the statement of operations. There were no expenses recorded in the three and six months

ended June 30, 2016.

The Company may pay potential development and regulatory milestone payments totaling up to $30.5 million for the first licensed product. vTv is eligible for an additional $77.0 million in potential sales-based milestones, as well as royalty payments, at mid-single digit royalty rates, based on tiered sales of the first commercialized licensed product. 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. The Company will be responsible for the worldwide development and commercialization of the licensed products, at its cost.

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 financial statements and related notes included in Part I, Item 1 of this report.

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

Overview

We are a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule oncology drugs directed against tumor and immune cell targets that control key metabolic pathways in the tumor microenvironment. Tumor metabolism and tumor immunology have emerged as promising new interrelated fields for cancer drug discovery, and recent clinical successes with therapeutic agents in each field have demonstrated the potential to create fundamentally new therapies for cancer patients. We are developing agents that take advantage of the unique metabolic requirements of tumor cells and cancer-fighting immune cells such as cytotoxic T-cells. Our lead product candidate, CB-839, is an internally discovered, first-in-class inhibitor of glutaminase, a critical enzyme in tumor cells. We are currently evaluating CB-839 in Phase 1 clinical trials in solid and hematological tumors. CB-839 administered as a single agent has resulted in clinical responses in renal cell cancer and acute myeloid leukemia, or AML, and clinical benefits in several other tumor types. We are currently enrolling patients in a series of combination Phase 1b cohorts in specific solid tumor types and AML. We are also planning to evaluate the immune-enhancing activity of CB-839 in a separate Phase 1/2 trial in the third quarter of 2016. We anticipate clinical updates in both renal cell carcinoma, or RCC, and triple negative breast cancer, or TNBC, in the fourth quarter of 2016. Our second product candidate, CB-1158, is a first-in-class immuno-oncology metabolic checkpoint inhibitor targeting arginase, an immunosuppressive enzyme in myeloid-derived suppressor cells responsible for T-cell suppression. In July 2016, we announced the acceptance of the Investigational New Drug application, or IND, by the U.S. Food and Drug Administration, or FDA. We intend to initiate a Phase 1 clinical trial with CB-1158 in the third quarter of 2016. We also have a third program directed towards the development of inhibitors of the tumor metabolism target hexokinase II and ongoing research efforts that are focused on discovering additional product candidates against novel tumor and immune cell metabolism targets.

Recent Developments

CB-839

Our lead product candidate, CB-839 is a potent, selective, reversible and orally bioavailable inhibitor of human glutaminase. CB-839 binds to a unique site on glutaminase that is distinct from the site that binds glutamine, thereby reducing the potential for undesirable side effects due to inhibition of other enzymes and receptors that bind glutamine. CB-839 takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. In preclinical studies, CB-839 demonstrated broad antitumor activity in cell lines, inhibited the growth of human tumors in animal models, and was well tolerated in animals at doses above those shown to inhibit tumor growth. CB-839 was also synergistic with several approved cancer therapeutics that are part of the current standard of care.

The single agent safety and tolerability of CB-839 has been assessed in three Phase 1 clinical trials in patients with solid tumors, or CX-839-001, multiple myeloma or non-Hodgkin's lymphoma, or CX-839-002, and acute myeloid leukemia, CX-839-003. The optimal dose and schedule of single agent CB-839, 600-800 mg twice daily, or BID, with food, has been well tolerated across all three Phase 1 studies. An initial observation of Grade 3/4 increases in liver function enzymes was reduced to a rate of less than 2% with this regimen. Single agent objective responses have been observed in patients with metastatic renal cell cancer (a Partial Response, or PR), and acute myeloid leukemia (a Complete Response with incomplete recovery of peripheral blood counts, or CRi). Furthermore, 52% of patients with renal cell cancer have had stable disease or better, with several patients remaining on study. We have observed long lasting stable disease in renal cell cancer patients, ranging from 63 days to more than 17 months. These results were presented in November 2015 at the combined EORTC/NCI/AACR meeting and were updated at the 2016 American Society of Clinical Oncology, or ASCO, annual meeting in June.

In addition to single agent cohorts, we also initiated enrollment in six Phase 1b combination cohorts, one in which CB-839 is being combined with paclitaxel in patients with triple-negative breast cancer with everolimus (marketed as Afinitor) in renal cell cancer, or RCC, with erlotinib (marketed as Tarceva) in patients with EGFR-mutated non-small cell lung cancer, or NSCLC, with dexamethasone in patients with multiple myeloma, or MM, or with pomalidomide (marketed as Pomalyst) and dexamethasone in patients with multiple myeloma, and with azacitidine (marketed as Vidaza) in front-line AML.

Combination data from the Phase 1 solid tumor trial in RCC and TNBC were presented at the June 2016 ASCO meeting. Ten RCC patients, with a median of two prior therapies, were treated in combination with 10 mg daily everolimus. The overall disease control rate was 80%, including one partial response; among eight clear cell and papillary patients, the disease control rate was 100%. The median time on study for these patients was 6.5+ months, exceeding the expected progression free survival of everolimus alone in this population. Time on treatment was equal to, or greater than, the time on prior therapy for most patients, and seven of eight patients remained on study. The combination of CB-839 and everolimus has been well tolerated to date. There was one case of dose-limiting, grade 3 pruitic rash at the 400 mg dose level, which led to a reduction in the dose of everolimus for that patient.

Fifteen triple-negative breast cancer patients were treated with doses of CB-839 of 400, 600 or 800 mg twice daily in combination with 80 mg/m2 IV paclitaxel, weekly, three weeks out of four. The majority of patients had received at least three prior lines of therapy. Six patients received five or more prior therapies in the advanced/metastatic setting. Most patients had received prior taxanes in either the neo-adjuvant (n=7) or metastatic (n=5) setting. Among patients treated with CB-839 doses of at least 600 mg (n=8), there were three partial responses (38%) and disease control (response or stable disease) in seven patients (88%). Two of the partial responses were observed in patients refractory to paclitaxel in a prior course of therapy. The combination of CB-839 and paclitaxel has been well tolerated to date, with adverse events that have been manageable and reversible. There was one case of dose-limiting, recurrent grade 3 neutropenia at the 400 mg dose level, which led to a reduction in the dose of paclitaxel for that patient.

In April 2016, we presented preclinical data at the American Association for Cancer Research, or AACR. We reported preclinical anti-tumor activity of CB-839 in combination with an anti-PD-L1 or an anti-PD-1 antibody. The combination of CB-839 and anti-PD-L1 or anti-PD-1 substantially increased the number of tumor regressions seen in the CT-26 syngeneic colon carcinoma model. Synergistic effects with CB-839 and anti-PD-L1 were also observed in a B16 melanoma model. We recently initiated a Phase 1/2 trial, CX-839-004, utilizing CB-839 in combination with nivolumab in patients with renal cell cancer, melanoma and non-small cell lung cancer. The Phase 1/2 study will assess the safety, pharmacokinetics and pharmacodynamics of CB-839 and nivolumab. We plan to enroll patients with clear cell renal cell carcinoma who are either naïve to checkpoint inhibitors, or were recently treated with nivolumab without tumor response, as well as melanoma and non-small cell lung cancer patients who have received anti-PD-1 monotherapy as their most recent line of therapy without tumor response.

Based on data generated from an academic research group at Case Western Reserve University, single agent CB-839 inhibits the growth of colorectal carcinomas with PIK3CA mutations in immunocompromised mice, but CRC tumors with a normal PIK3CA gene were not inhibited. These results have led to an investigator-sponsored trial at Case Western Reserve University which is planned to start in the second half of 2016 and will be enrolling colorectal cancer patients with a PIK3CA mutation for treatment with a combination of CB-839 and capecitabine.

Pending input from the FDA on the results of our Phase 1 trials, we plan to initiate one or more randomized, placebo-controlled Phase 2 clinical trials, likely in 2017, to study CB-839 in combination with approved conventional therapies and/or checkpoint inhibitors.

CB-1158

Our second product candidate, CB-1158, is a an orally bioavailable inhibitor of arginase, an immunosuppressive enzyme in myeloid-derived suppressor cells responsible for T-cell suppression. 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, or 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 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.

In April 2016, we presented data at AACR which demonstrated that CB-1158 has single agent activity in animal models. Inhibition of tumor growth was accompanied by an increase in the local concentration of arginine, and the induction of multiple pro-inflammatory changes in the tumor microenvironment. CB-1158 increased CD8+ T-cell infiltrates in a lung tumor model. The addition of CB-1158 to anti-CTLA-4 and anti-PD-1, significantly inhibited tumor growth and reduced metastases in a mouse model that was resistant to dual checkpoint inhibitor therapy. CB-1158 was well tolerated as a single agent and in combination with checkpoint inhibitors in animal studies. We believe preclinical in vitro and in vivo data also predict good oral bioavailability of CB-1158 in humans. In July 2016, we announced the acceptance of the IND by the FDA. We intend to initiate a Phase 1 clinical trial with CB-1158 in the third quarter of 2016.

Critical Accounting Policies and Estimates

There have been no material changes in our critical accounting policies during the six months ended June 30, 2016, 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, 2015, filed with the SEC.

Financial Overview

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. 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; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies;
- license fees and milestone payments related to our licensing agreements.

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 six months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(in thousands)			
Development:				
CB-839 (Glutaminase inhibitor)	$3,101	$3,401	$5,646	$6,894
CB-1158 (Arginase inhibitor)	3,678	—	7,186	—
Total development	6,779	3,401	12,832	6,894
Preclinical and research:				

Arginase inhibitors	—	1,982	722	3,401
Other preclinical and research	997	150	1,288	868
Total preclinical and research	997	2,132	2,010	4,269
Total Research and Development	$7,776	$5,533	$14,842	$11,163

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

We have exclusive license agreements with Mars, Inc., by and through its Mars Symbioscience division, to develop and commercialize their portfolio of arginase inhibitors and with High Point Pharmaceuticals, LLC and TransTech Pharma LLC, or collectively TransTech, (which was subsequently assigned by TransTech to its parent company, vTv Therapeutics LLC) to develop and commercialize their hexokinase II inhibitors. These license agreements will result in higher research and development expenses in the future.

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 trial enrollment, 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 and amortization expense and other supplies. We expect to incur additional expenses as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of the NASDAQ Global Select Market on which our securities are traded, and other administration and professional services.

Results of Operations

Comparison of the Three Months Ended June 30, 2016 and 2015

	Three Months Ended June 30,		Change	
	2016	2015	$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$7,776	$5,533	$2,243	41%
General and administrative	2,665	2,341	324	14%
Total operating expenses	10,441	7,874	2,567	33%
Loss from operations	(10,441)	(7,874)	(2,567)	33%
Interest income, net	83	56	27	*
Net loss	$(10,358)	$(7,818)	$(2,540)	32%

* Percentage not meaningful.

Research and Development. Research and development expenses increased $2.2 million, or 41%, from $5.5 million for the three months ended June 30, 2015 to $7.8 million for the three months ended June 30, 2016. The increase of $2.2 million was due to an increase of $1.8 million primarily related to increased development activities in our arginase inhibitors program as we submitted an IND in June 2016, an increase of $0.6 million in personnel-related costs primarily due to higher headcount, salary increases and stock-based compensation expense, offset by a decrease of $0.2 million related to our licensing arrangements.

General and Administrative. General and administrative expenses increased $0.3 million, or 14%, from $2.3 million for the three months ended June 30, 2015 to $2.7 million for the three months ended June 30, 2016. The increase of $0.3 million was due to an increase of $0.3 million in personnel-related costs as a result of higher headcount, salary

increases and stock-based compensation expense, an increase of $0.2 million in professional services primarily related to higher legal costs associated with our in-licensing agreements, offset by a decrease of $0.2 million for a payment to a third party related to a terminated license arrangement.

Interest Income. Interest income increased $27,000, from $56,000 for the three months ended June 30, 2015 to $83,000 for the three months ended June 30, 2016. The increase of $27,000 was primarily due to higher interest income generated from our cash equivalents and investment balances compared to the same period in the prior year.

Comparison of the Six Months Ended June 30, 2016 and 2015

	Six Months Ended June 30,		Change	
	2016	2015	$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$14,842	$11,163	$3,679	33%
General and administrative	5,256	4,578	678	15%
Total operating expenses	20,098	15,741	4,357	28%
Loss from operations	(20,098)	(15,741)	(4,357)	28%
Other income, net	158	65	93	*
Net loss	$(19,940)	$(15,676)	$(4,264)	27%

* Percentage not meaningful.

Research and Development. Research and development expenses increased $3.7 million, or 33%, from $11.2 million for the six months ended June 30, 2015 to $14.8 million for the six months ended June 30, 2016. The increase of $3.7 million was due to an increase of $3.1 million primarily related to increased development activities in our arginase inhibitors program as we submitted an IND in June 2016, an increase of $1.2 million in personnel-related costs primarily due to higher headcount, salary increases and stock-based compensation expense, offset by a decrease of $0.6 million related to our licensing arrangements.

General and Administrative. General and administrative expenses increased $0.7 million, or 15%, from $4.6 million for the six months ended June 30, 2015 to $5.3 million for the six months ended June 30, 2016. The increase of $0.7 million was due to an increase of $0.7 million in personnel-related costs as a result of higher headcount, salary increases and stock-based compensation expense, an increase of $0.1 million in professional services primarily related to higher legal costs associated with our in-licensing agreements, offset by a decrease of $0.2 million for a payment to a third party related to a terminated license arrangement.

Interest Income. Interest income increased $93,000, from $65,000 for the six months ended June 30, 2015 to $0.2 million for the six months ended June 30, 2016. The increase of $93,000 was primarily due to higher interest income generated from our cash equivalents and investment balances compared to the same period in the prior year.

Liquidity and Capital Resources

As of June 30, 2016, we had cash, cash equivalents and investments totaling $60.4 million. Our operations have been financed primarily by net proceeds from the sale of shares of our preferred stock, our initial public offering in October 2014 and our at-the-market, or ATM, offering program.

In November 2015, 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 $150 million of our common stock. Up to $50 million of the maximum aggregate offering price of $150 million may be issued and sold pursuant to an ATM program under a sales agreement with Cowen and Company LLC, which is acting as our sales agent and underwriter. During the six months ended June 30, 2016, we sold an aggregate of 715,383 shares of common stock pursuant to the ATM program, at an average price of approximately $6.21 per share for gross proceeds of $4.4 million, resulting in net proceeds of $4.0 million after deducting underwriting fees and offering expenses. As of June 30, 2016, $145.6 million of our common stock remained available for sale pursuant to the shelf registration statement, of which $45.6 million may be sold pursuant to the ATM program, 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 June 30, 2016 will be sufficient for us to meet our current operating plan for at least the next twelve months. 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 equity and/or debt financing. We may also consider 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:

	Six Months Ended June 30,	
	2016	2015
	(in thousands)	
Cash used in operating activities	$(15,248)	$(13,627)
Cash provided by (used in) investing activities	$12,299	$(77,306)
Cash provided by financing activities	$4,170	$283

Cash Flows from Operating Activities

Cash used in operating activities for the six months ended June 30, 2016 was $15.2 million. Our net loss of $19.9 million was offset in part by non-cash charges of $2.1 million of stock-based compensation and $0.5 million for depreciation and amortization. The change in operating assets and liabilities of $2.1 million was primarily due to the timing of payments for our research and development activities.

Cash used in operating activities for the six months ended June 30, 2015 was $13.6 million. Our net loss of $15.7 million was offset in part by non-cash charges of $0.2 million for depreciation and amortization and $1.4 million of stock-based compensation. The change in operating assets and liabilities of $0.3 million was primarily due to the

timing of payments for our clinical trials and manufacturing activities.

Cash Flows from Investing Activities

Cash provided by investing activities was $12.3 million for the six months ended June 30, 2016 and was related to the sale or maturity of investments of $36.6 million, offset by purchase of investments of $24.1 million and purchase of property and equipment of $0.2 million.

Cash used in investing activities was $77.3 million for the six months ended June 30, 2015 and was related to the purchase of investments of $81.6 million and purchase of property and equipment of $0.3 million, partially offset by the sale or maturity of investments of $4.5 million.

Cash Flows from Financing Activities

Cash provided by financing activities was $4.2 million for the six months ended June 30, 2016 and was related to net proceeds from the issuance of common stock through our ATM program of $4.0 million and issuance of common stock upon the exercise of stock options and employee stock plan purchases of $0.2 million.

Cash provided by financing activities was $0.3 million for the six months ended June 30, 2015 and was related to the issuance of common stock upon the exercise of stock options and employee stock plan purchases.

Contractual Obligations and Other Commitments

There have been no material changes to the contractual obligations during the three months ended June 30, 2016, as compared to those disclosed in our Annual Report on Form 10-K for the year ending December 31, 2015.

Off-Balance Sheet Arrangements

During 2015 and the three months ended June 30, 2016, we did not have any off balance sheet arrangements.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for the 2016 annual period and with early adoption permitted. We will include the required disclosures in our December 31, 2016 annual financial statements to the extent that they are applicable.

In February 2016, the FASB issued ASU 2016-02, Leases. The ASU requires management to recognize lease assets and lease liabilities by lessees for all operating leases. The ASU is effective for the annual period beginning after December 15, 2018 and interim periods therein on a modified retrospective basis. We are currently assessing the impact the adoption of ASU 2016-02 will have on our financial statements.

In March 2016, FASB issued ASU 2016-09, Compensation – Stock Compensation. ASU 2016-09 simplified certain aspects of the accounting for share-based payment transactions, including income taxes, classification of awards and classification in the statement of cash flows. ASU 2016-09 is effective for the annual period beginning after December 15, 2016, and interim periods therein. We are currently assessing the impact of adopting ASU 2016-09 will have on our financial statements.

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 June 30, 2016, we had cash, cash equivalents and investments of $60.4 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 a 1% change in interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates. We had no outstanding debt as of June 30, 2016.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, 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 quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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

You should carefully consider the following risk factors, in addition to the other information contained in this report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be harmed. This report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report. 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 June 30, 2016, 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 $32.6 million and $19.9 million for 2015 and the six months ended June 30, 2016, respectively. As of June 30, 2016, we had an accumulated deficit of $104.4 million. To date, we have financed our operations primarily through private placements of our preferred stock, our initial public offering in October 2014 and our at-the-market program. We have devoted substantially all of our financial resources and efforts to research and development. We are currently in Phase 1 clinical trials on our lead product candidate, CB-839, and 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 into and through clinical trials our existing clinical product candidates, CB-839, a glutaminase inhibitor for the treatment of solid and hematological tumors, and CB-1158, our arginase inhibitor;
- continue the preclinical development of our hexokinase II inhibitor program and advance a candidate into clinical trials;
- identify additional product candidates and advance them into preclinical development;
- 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; and

- acquire or in-license other product candidates and technologies.

To become and remain profitable, we 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 CB-1158, 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, preclinical development, laboratory testing and clinical trials for our product candidates, in particular CB-839 and CB-1158;
- the costs, timing and outcome of any regulatory review of our product candidate, CB-839 and CB-1158;
- the cost of our hexokinase II inhibitor program, and 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;
- 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.

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 collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. 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 collaborations, strategic alliances or licensing arrangements 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 clinical trials of our product candidate. We are currently evaluating CB-839 in Phase 1 clinical trials. In July

2016, we announced the acceptance of the IND application by the FDA. We intend to initiate a Phase 1 clinical trial with CB-1158 in the third quarter of 2016. 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, as a new business, 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.

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 and hexokinase 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 and hexokinase 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 and hexokinase 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 products candidate, CB-839, which is being evaluated in Phase 1 clinical trials. In July 2016, we announced the acceptance of the IND application by the FDA. We intend to initiate a Phase 1 clinical trial with CB-1158 in the third quarter of 2016. Our hexokinase II inhibitor program is in preclinical development. Because of the early stage of our development efforts and our unproven and novel approach to discovery and development of product candidates, we do not have a clearly defined clinical development path. 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 CB-1158. The success of CB-839, CB-1158 and our hexokinase II inhibitor programs 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;
- 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; and
- enforcing and defending intellectual property rights and claims.

21

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 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, 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