

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K/A  
(Amendment No. 1)

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest reported) February 10, 2020

**BRICKELL BIOTECH, INC.**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

000-21088  
(Commission File  
Number)

93-0948554  
(IRS Employer  
Identification No.)

5777 Central Avenue, Suite 102  
Boulder, CO 80301  
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: (720) 505-4755

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.01 per share	BBI	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

On August 31, 2019, the Delaware corporation formerly known as “Vical Incorporated” completed its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of June 2, 2019, as amended by Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated August 20, 2019, and as further amended on August 30, 2019 (the “**Merger Agreement**”), by and among Vical Incorporated (“**Vical**”), Brickell Biotech, Inc. (“**Brickell**”) and Victory Subsidiary, Inc., a wholly-owned subsidiary of Vical (“**Merger Sub**”), pursuant to which Merger Sub merged with and into Brickell, with Brickell surviving the merger as a wholly-owned subsidiary of Vical (the “**Merger**”). Additionally, on August 31, 2019, immediately after the completion of the Merger, the Company changed its name from “Vical Incorporated” to “Brickell Biotech, Inc.” (the “**Company**”).

On August 31, 2019, in connection with, and prior to the consummation of, the Merger, Vical effected a reverse stock split of its common stock, par value \$0.01 per share, at a ratio of 1-for-7 (the “**Reverse Stock Split**”).

On September 3, 2019, the Company filed a Current Report on Form 8-K (the “**Original Form 8-K**”) reporting, among other items, the consummation of the Merger. This Amendment No. 1 to Current Report on Form 8-K amends the Original Form 8-K to provide the historical audited consolidated financial statements of Brickell as of December 31, 2017 and 2018, and for the years ended December 31, 2018 and 2017, as retrospectively adjusted to give effect to the Reverse Stock Split and the exchange of shares in the merger to share and per-share amounts in such financial information.

#### **Item 9.01 Financial Statements and Exhibits.**

##### *Financial Statements*

Brickell’s audited financial statements for the years ended December 31, 2018 and 2017 are filed herewith as Exhibit 99.1 and incorporated by reference herein.

##### *Exhibits*

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">23.1</a>	Consent of Independent Registered Public Accounting Firm
<a href="#">99.1</a>	Audited Financial Statements of Brickell Biotech, Inc. for the years ended December 31, 2018 and 2017

**SIGNATURES**

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

Date: February 10, 2020

**Brickell Biotech, Inc.**

By: /s/ Robert B. Brown  
Name: Robert B. Brown  
Title: Chief Executive Officer

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-30181) pertaining to the 1992 Stock Plan of Vical Incorporated,
- (2) Registration Statement (Form S-8 No. 333-80681) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (3) Registration Statement (Form S-8 No. 333-60293) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (4) Registration Statement (Form S-8 No. 333-66254) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (5) Registration Statement (Form S-8 No. 333-97019) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (6) Registration Statement (Form S-8 No. 333-107581) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (7) Registration Statement (Form S-8 No. 333-116951) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (8) Registration Statement (Form S-8 No. 333-135266) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (9) Registration Statement (Form S-8 No. 333-143885) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (10) Registration Statement (Form S-8 No. 333-169344) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (11) Registration Statement (Form S-8 No. 333-183215) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (12) Registration Statement (Form S-8 No. 333-190343) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (13) Registration Statement (Form S-8 No. 333-213034) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (14) Registration Statement (Form S-8 No. 333-219804) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (15) Registration Statement (Form S-3 No. 333-225208) of Vical Incorporated, and
- (16) Registration Statement (Form S-8 No. 333-233698) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated and the Equity Incentive Plan of Brickell Biotech, Inc.

of our report dated July 2, 2019 (except for the merger described in Note 1 and Note 13, as to which the date is February 10, 2020), with respect to the consolidated financial statements of Brickell Biotech, Inc., included in this Current Report on Form 8-K.

/s/ Ernst & Young LLP

Denver, Colorado  
February 10, 2020

**BRICKELL BIOTECH, INC.**

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## Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Brickell Biotech, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Brickell Biotech, Inc. (the Company) as of December 31, 2018 and 2017, the related statements of operations, redeemable convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

### The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017

Denver, Colorado

July 2, 2019

except for the merger described in Note 1 and Note 13, as to which the date is

February 10, 2020

**BRICKELL BIOTECH, INC.**  
**BALANCE SHEETS**

(In thousands, except share and per share data)

	December 31, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,067	\$ 5,399
Prepaid expenses and other current assets	204	89
Deferred sublicensing costs, current portion	—	342
Total current assets	<u>8,271</u>	<u>5,830</u>
Property and equipment, net	37	74
Intangible assets	441	441
Deferred sublicensing costs, net of current portion	—	342
Total assets	<u>\$ 8,749</u>	<u>\$ 6,687</u>
<b>Liabilities, redeemable convertible preferred stock and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 4,067	\$ 1,222
Accrued liabilities	3,272	3,456
Deferred revenue, current portion	8,117	1,709
Note payable, current portion	4,639	2,131
Total current liabilities	<u>20,095</u>	<u>8,518</u>
Contingent consideration	145	148
Redeemable convertible preferred stock warrant liability	242	486
Note payable, net of current portion	—	3,408
Deferred revenue, net of current portion	1,595	1,709
Total liabilities	<u>22,077</u>	<u>14,269</u>
Redeemable convertible preferred stock (Series A, B, C and C-1), \$0.01 par value, 4,182,943 shares authorized at December 31, 2018 and 2017; 1,256,466 shares issued and outstanding at December 31, 2018 and 2017; aggregate liquidation preference of \$46,985 and \$43,493 at December 31, 2018 and 2017, respectively	58,290	52,354
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Common stock, \$0.01 par value, 8,000,000 shares authorized at December 31, 2018 and 2017; 589,001 and 585,262 issued and outstanding at December 31, 2018 and 2017, respectively	6	6
Additional paid-in capital	—	—
Accumulated deficit	(71,624)	(59,942)
Total stockholders' deficit	<u>(71,618)</u>	<u>(59,936)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 8,749</u>	<u>\$ 6,687</u>

See accompanying notes to audited financial statements.

**BRICKELL BIOTECH, INC.**  
**STATEMENTS OF OPERATIONS**  
*(In thousands, except share and per share data)*

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Collaboration revenue	\$ 10,888	\$ 7,567
Operating expenses:		
Research and development	12,960	11,885
General and administrative	6,379	5,648
Total operating expenses	<u>19,339</u>	<u>17,533</u>
Loss from operations	(8,451)	(9,966)
Interest income	61	25
Interest expense	(1,090)	(1,049)
Change in fair value of redeemable convertible preferred stock warrant liability	244	(126)
Net loss	(9,236)	(11,116)
Accretion of redeemable convertible preferred stock to redemption value	(5,936)	(11,925)
Net loss attributable to common stockholders	<u>\$ (15,172)</u>	<u>\$ (23,041)</u>
Basic and diluted net loss per common share attributable to common stockholders	<u>\$ (25.85)</u>	<u>\$ (39.41)</u>
Shares used in computing basic and diluted net loss per share attributable to common stockholders	<u>586,962</u>	<u>584,628</u>

See accompanying notes to audited financial statements.



**BRICKELL BIOTECH, INC.**  
**STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**  
*(In thousands, except share data)*  
YEARS ENDED DECEMBER 31, 2018 AND 2017

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Carrying Value	Shares	Par Value			
Balance, December 31, 2016	1,053,895	\$ 32,685	584,399	\$ 6	\$ —	\$ (37,792)	\$ (37,786)
Stock based compensation	—	—	—	—	881	—	881
Issuance of common stock through exercise of stock option	—	—	863	—	10	—	10
Issuance of Series C-1 convertible preferred stock, net of issuance costs of \$120	202,571	7,744	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	11,925	—	—	(891)	(11,034)	(11,925)
Net loss	—	—	—	—	—	(11,116)	(11,116)
Balance, December 31, 2017	1,256,466	52,354	585,262	6	—	(59,942)	(59,936)
Effect of adoption of Topic 606	—	—	—	—	—	2,734	2,734
Stock based compensation	—	—	—	—	711	—	711
Issuance of common stock through exercise of stock option	—	—	3,739	—	45	—	45
Accretion of redeemable convertible preferred stock to redemption value	—	5,936	—	—	(756)	(5,180)	(5,936)
Net income	—	—	—	—	—	(9,236)	(9,236)
<b>Balance, December 31, 2018</b>	<b>1,256,466</b>	<b>\$ 58,290</b>	<b>589,001</b>	<b>\$ 6</b>	<b>\$ —</b>	<b>\$ (71,624)</b>	<b>\$ (71,618)</b>

See accompanying notes to audited financial statements.

**BRICKELL BIOTECH, INC.**  
**STATEMENTS OF CASH FLOWS**  
*(In thousands)*

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,236)	\$ (11,116)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	49	48
Change in fair value of convertible preferred stock warrant liability	(244)	126
Change in fair value of contingent consideration	(3)	(45)
Amortization of debt discounts and financing costs	489	358
Stock-based compensation	711	881
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(115)	545
Deferred sublicensing fees	—	513
Accounts payable	2,845	262
Accrued liabilities	(241)	1,587
Deferred revenue	9,712	(2,567)
Net cash provided by (used in) operating activities	<u>3,967</u>	<u>(9,408)</u>
<b>Cash flows from investing activities:</b>		
Capital expenditures	(12)	(11)
Net cash used in investing activities	<u>(12)</u>	<u>(11)</u>
<b>Cash flows from financing activities:</b>		
Principal payments made on note payable	(1,282)	(1,410)
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	7,764
Note payable issuance costs	(50)	—
Proceeds from the exercise of stock options	45	10
Net cash provided by (used in) financing activities	<u>(1,287)</u>	<u>6,364</u>
<b>Net increase (decrease) in cash and cash equivalents</b>	<u>2,668</u>	<u>(3,055)</u>
<b>Cash and cash equivalents—Beginning</b>	<u>5,399</u>	<u>8,454</u>
<b>Cash and cash equivalents—Ending</b>	<u>\$ 8,067</u>	<u>\$ 5,399</u>
<b>Supplement disclosure of cash flow information:</b>		
Interest paid	<u>\$ 608</u>	<u>\$ 699</u>
<b>Supplement disclosure of non-cash financing and investing activities:</b>		
Accretion of redeemable convertible preferred stock to redemption value	<u>\$ 5,896</u>	<u>\$ 11,897</u>
Accretion of redeemable convertible preferred stock issuance costs	<u>\$ 40</u>	<u>\$ 28</u>

See accompanying notes to audited financial statements.

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**NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS**

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Brickell Biotech, Inc. (the “Company”) was incorporated in the state of Delaware and commenced activities on September 17, 2009. The Company is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated therapeutics for the treatment of skin diseases. The Company’s pivotal Phase 3-ready clinical-stage product candidate, sofipironium bromide, is a proprietary new molecular entity. The Company is headquartered in Boulder, Colorado.

***Liquidity and Capital Resources***

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company has incurred significant operating losses and has an accumulated deficit as a result of ongoing efforts to develop product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the year ended December 31, 2018, the Company had a net loss of \$9.2 million and net cash provided by operating activities of \$4.0 million. As of December 31, 2018, the Company had cash and cash equivalents of \$8.1 million and an accumulated deficit of \$71.6 million.

The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company’s research and development activities. The Company plans to finance operations through equity or debt financing arrangements, and/or third-party collaboration funding. Additional funding will be required in the future to maintain its present and proposed research activities. There can be no assurance that additional equity or debt financing will be available on acceptable terms, if at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern for a period of twelve months subsequent to the issuance of these financial statements.

***Merger of Brickell Biotech, Inc. and Vical Incorporated***

On August 31, 2019, the Delaware corporation formerly known as “Vical Incorporated,” completed a reverse merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of June 2, 2019, as amended by Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated August 20, 2019, and as further amended on August 30, 2019 (the “Merger Agreement”), by and among Vical Incorporated (“Vical”), Brickell and Victory Subsidiary, Inc., a wholly-owned subsidiary of Vical formed in connection with the merger (the “Merger Sub”), pursuant to which the Merger Sub merged with and into Brickell, with Brickell surviving the merger as a wholly-owned subsidiary of Vical (the “Merger”). Additionally, on August 31, 2019, immediately after the completion of the Merger, the Company changed its name from “Vical Incorporated” to “Brickell Biotech, Inc.”

On August 31, 2019, in connection with, and prior to the consummation of the Merger, Vical effected a reverse stock split of its common stock, par value \$0.01 per share, at a ratio of 1-for-7 (the “Reverse Stock Split”). On August 31, 2019, all shares of preferred stock of the Company converted into shares of common stock of the Company on a one-for-one basis. At the effective date of the Merger, the Company issued shares of its common stock to its stockholders, at an exchange rate of approximately 2.4165 shares of common stock in exchange for each share of the Company’s common stock outstanding immediately prior to the Merger (the “Exchange Ratio”). The exchange rate was calculated by a formula that was determined through arms-length negotiations between the Vical and the Company. Unless otherwise noted herein, references to share and per-share amounts give retroactive effect to the Reverse Stock Split and the Exchange Ratio, which was effected upon the Merger.

Immediately following the consummation of the Merger, there were 7,810,680 shares of common stock issued and outstanding, with the Company’s former securityholders beneficially owning approximately 57% of the outstanding shares of common stock and Vical’s former securityholders beneficially owning approximately 43% of the outstanding shares of common stock.

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**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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***Basis of Presentation***

The accompanying financial statements are presented in U.S. dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”).

### ***Use of Estimates in the Preparation of Financial Statements***

The preparation of financial statements, in conformity with US 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 balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, accrued research and development expenses, intangible assets, other long-lived assets, redeemable convertible preferred stock, warrants, stock-based compensation, and the valuation of deferred tax assets. The Company bases its estimates on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

### ***Risks and Uncertainties***

The Company's business is subject to significant risks common to early-stage companies in the pharmaceutical industry including, but not limited to, the ability to develop appropriate formulations, scale up and production of the compounds, dependence on collaborative parties, uncertainties associated with obtaining and enforcing patents, clinical success, the lengthy and expensive regulatory approval process, compliance with regulatory requirements, competition from other products; uncertainty of broad adoption of its approved products, if any, by physicians and patients; significant competition; ability to manage third-party manufacturers, suppliers and contract research organizations ("CROs") and obtaining additional financing to fund the Company's efforts.

The product candidates developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") and foreign regulatory agencies prior to commercial sales in the United States or foreign jurisdictions, respectively. There can be no assurance that the Company's current and future product candidates will receive the necessary approvals. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company's business and its financial condition.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to complete clinical studies and launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid debt instruments with an original maturity of three months or less from date of purchase to be cash equivalents. Cash equivalents, which are stated at cost, consist primarily of amounts held in short-term money market accounts with highly rated financial institutions.

### ***Concentrations of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash balances in several accounts with one financial institution which, from time to time, are in excess of federally insured limits.

### ***Property and Equipment***

Property and equipment is stated at cost, less accumulated depreciation. Expenditures for major betterments and additions are charged to the asset accounts, while replacements, maintenance and repairs, which do not improve or extend the lives of the respective assets, are charged to expense as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Depreciation expense amounted to approximately \$49,000 and \$48,000 for the years ended December 31, 2018 and 2017, respectively. Accumulated depreciation amounted to approximately \$146,000 and \$97,000 as of December 31, 2018 and 2017, respectively.

### ***Impairment of Long-Lived Assets***

The Company assesses changes in the performance of its product candidates in relation to its expectations, and industry, economic and regulatory conditions and makes assumptions regarding estimated future cash flows in evaluating the value of its property and equipment, and in-process research and development ("IPR&D").

The Company periodically evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, an impairment loss is recognized to the extent the carrying amount of the impaired asset exceeds its fair value.

IPR&D represents the fair value assigned to incomplete research projects that the Company acquires in business acquisitions, which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized and accounted for as indefinite-lived intangible assets are subject to impairment testing until completion or abandonment of the project. The Company tests IPR&D for impairment at least annually, or more frequently, if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. If the Company discontinues or abandons a program related to IPR&D and determines that there are no other indicators of value, the Company will impair the entire amount of the related intangible asset. There were no impairments of IPR&D during the years ended December 31, 2018 and 2017.

#### **Fair Value Measurements**

Fair value is the price that the Company would receive to sell an asset or pay to transfer a liability in a timely transaction with an independent counterparty in the principal market or in the absence of a principal market, the most advantageous market for the asset or liability. A three-tier hierarchy is established to distinguish between (1) inputs that reflect the assumptions market participants would use in pricing an asset or liability developed based on market data obtained from sources independent of the reporting entity (observable inputs) and (2) inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing an asset or liability developed based on the best information available in the circumstances (unobservable inputs), and establishes a classification of fair value measurements for disclosure purposes.

The hierarchy is summarized in the three broad levels listed below.

**Level 1**—quoted prices in active markets for identical assets and liabilities

**Level 2**—other significant observable inputs (including quoted prices for similar assets and liabilities, interest rates, credit risk, etc.)

**Level 3**—significant unobservable inputs (including the Company's own assumptions in determining the fair value of assets and liabilities)

The following tables set forth the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy as of December 31, 2018 and 2017 (in thousands):

	<b>December 31, 2018</b>		
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Assets:</b>			
Money market funds	\$ 8,067	\$ —	\$ —
<b>Total</b>	<b>\$ 8,067</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Liabilities:</b>			
Redeemable convertible preferred stock warrant liability	\$ —	\$ —	\$ 242
Contingent consideration	—	—	145
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 387</b>
	<b>December 31, 2017</b>		
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Assets:</b>			
Money market funds	\$ 5,399	\$ —	\$ —
<b>Total</b>	<b>\$ 5,399</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Liabilities:</b>			
Redeemable convertible preferred stock warrant liability	\$ —	\$ —	\$ 486
Contingent consideration	—	—	148
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 634</b>

### ***Fair Value of Financial Instruments***

The following methods and assumptions were used by the Company in estimating the fair values of each class of financial instrument disclosed herein:

***Money market funds***—The carrying amounts reported in the balance sheets approximate their fair values due to their short-term nature and/or market rates of interest (Level 1 of the fair value hierarchy).

***Contingent consideration***—These amounts represent future payments in conjunction with various business combinations. The ultimate amount of future payments is based on specified future criteria, such as the achievement of certain future development and regulatory milestones. The Company evaluates its estimates of the fair value of contingent consideration on a periodic basis. The fair value of the contingent consideration was determined by a third-party valuation firm applying the income approach. This approach estimates the fair value of the contingent consideration related to the achievement of future development and regulatory milestones by assigning an achievement probability and date of expected completion to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The probability of success of each milestone assumes that the prerequisite developmental milestones are successfully completed and is based on the asset's current stage of development and anticipated regulatory requirements. The probability of success for each milestone is determined by multiplying the preceding probabilities of success. The unobservable inputs (Level 3 of the fair value hierarchy) to the valuation models that have the most significant effect on the fair value of the Company's contingent consideration are the probabilities that certain in-process development projects will meet specified development milestones, including ultimate approval by the FDA, with individual cumulative probabilities ranging from 2.1% to 20.9%. Other unobservable inputs used in this approach include: risk-adjusted discount rates ranging from 15.5% to 27.1% and estimates of the timing of the achievement of the various product development, regulatory approval and sales milestones.

***Redeemable convertible preferred stock warrant liability***—These amounts represent potential future obligations to transfer assets to the holders at a future date. The Company remeasures these warrants to current fair value at each balance sheet date, and any change in fair value is recognized as a change in fair value of warrant liability in the statements of operations. The Company estimated the fair value of these warrants at the respective balance sheet dates using the Black-Scholes option-pricing model (Level 3 of the fair value hierarchy table) (see further discussion in Note 7).

Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The most significant unobservable inputs used in the fair value measurement of the convertible preferred stock warrant liability are the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

The fair value of the outstanding convertible preferred stock warrants was remeasured as of December 31, 2018 using the Black-Scholes option-pricing model with the following assumptions: contractual term of 7.1 years, expected volatility of 30.0%, risk-free rate of 2.59%, and expected dividend yield of 0%.

***Fair Value of Redeemable Convertible Preferred Stock***. The fair value of the shares of the convertible preferred stock underlying the preferred stock warrants has historically been determined by a third-party valuation firm. Because there has been no public market for the Company's convertible preferred stock, the third-party valuation firm has determined fair value of the convertible preferred stock at each balance sheet date by considering a number of objective and subjective factors, including valuation of comparable companies, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors.

***Remaining Term***. The Company derived the expected term based on the time from the balance sheet date until the preferred stock warrant's expiration date.

***Expected Volatility***. Since the Company was a private entity with no historical data regarding the volatility of its preferred stock, the expected volatility used is based on volatility of a group of similar entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

***Risk-Free Interest Rate***. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term of the warrants.

***Expected Dividend Rate***. The Company has never paid any dividends and does not plan to pay dividends in the foreseeable future and, therefore, used an expected dividend rate of zero in the valuation model.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows (in thousands):

	<b>Redeemable Convertible Preferred Stock Warrant Liability</b>	<b>Contingent Consideration Liabilities</b>
Fair value as of December 31, 2016	\$ 360	\$ 193
Change in fair value	126	(45)
Fair value as of December 31, 2017	486	148
Change in fair value	(244)	(3)
Fair value as of December 31, 2018	<u>\$ 242</u>	<u>\$ 145</u>

#### ***Redeemable Convertible Preferred Stock***

Redeemable convertible preferred stock is classified as a mezzanine instrument outside of the Company's capital accounts. Accretion of redeemable convertible preferred stock includes the greater of an adjustment to fair market value or the accrual of dividends on and accretion of issuance costs of the Company's redeemable convertible preferred stock. The carrying values of the redeemable convertible preferred stock are increased by periodic accretion to their respective redemption values, using the effective interest method, from the date of issuance to the earliest date the holders can demand redemption. These increases are recorded as charges against additional paid-in capital balance until the additional paid-in capital balance is reduced to zero. At that time, additional accretion adjustments are recorded as additions to accumulated deficit.

Preferred stock issuance costs represent costs related to the Company issuing redeemable convertible preferred stock. These amounts are included as a reduction of redeemable convertible preferred stock and are amortized over the estimated redemption period. Amortization of preferred stock issuance costs amounted to approximately \$40,000 and \$28,000 for the years ended December 31, 2018 and 2017, respectively.

#### ***Redeemable Convertible Preferred Stock Warrants***

The Company accounts for warrants to purchase shares of its redeemable convertible preferred stock as liabilities at their estimated fair value because the underlying shares are redeemable, which may obligate the Company to transfer assets to the holders at a future date. The warrants are subject to remeasurement to fair value at each balance sheet date, and any fair value adjustments are recognized as change in fair value of redeemable convertible preferred stock warrant liability in the statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the redeemable convertible preferred stock warrants, conversion of redeemable convertible preferred stock into common stock, or until holders of the redeemable convertible preferred stock can no longer trigger a deemed liquidation event. At that time, the redeemable convertible preferred stock warrant liability will be adjusted to fair value in the statements of operations with the final fair value reclassified to equity.

#### ***Revenue Recognition***

Effective January 1, 2018, the Company adopted Accounting Standards Update ("ASU") 2018-18, Collaborative Arrangements: Clarifying the Interaction Between Topic 808 and Topic 606 ("Topic 808" or "ASU 2018-18") using the retrospective method and ASU 2014-09, Revenue from Contracts with Customers (Topic 606) ("Topic 606" or "ASU 2014-09") using the modified retrospective method which consisted of applying and recognizing the cumulative effect of Topic 606 at the date of initial application. Topic 606 supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") Topic 605, Revenue Recognition ("Topic 605"), including most industry-specific revenue recognition guidance throughout the Industry Topics of the ASC. All periods prior to the adoption date of Topic 606 have not been restated to reflect the impact of the adoption of Topic 606, but continue to be accounted for and presented under Topic 605.

The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers the Company 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 Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. 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.

To date, the Company's drug candidates have not been approved for sale by the FDA and the Company has not generated or recognized any revenue from the sale of products.

In March 2015, the Company entered into a license, development and commercialization agreement with Kaken Pharmaceutical, Co., Ltd. (“Kaken”), which is referred to as the “Kaken Agreement.” Under the Kaken Agreement, the Company granted to Kaken an exclusive right to develop, manufacture and commercialize the Company’s sofipronium bromide compound (formerly BBI-4000), a topical anticholinergic, in Japan and certain other Asian countries (the “Territory”). In exchange, Kaken paid the Company an upfront, non-refundable payment of \$11.0 million (the “upfront fee”). In addition, the Company is entitled to receive aggregate payments of up to \$10.0 million upon the achievement of specified development milestones, and \$30.0 million upon the achievement of commercial milestones, as well as tiered royalties based on a percentage of net sales of licensed products in the Territory. The Kaken Agreement further provides that Kaken will be responsible for funding all development and commercial costs for the program in the Territory and, until such time, if any, as Kaken elects to establish its own source of supply of drug product, Kaken can purchase product supply from the Company to perform all non-clinical studies, and Phase I and Phase II clinical trials in Japan at cost. Kaken is also required to enter into negotiations with the Company, to supply the Company, at cost, with clinical supplies to perform Phase III clinical trials in the U.S.

*Collaboration arrangement subsequent to adoption of Topic 606*

The Company evaluates collaboration arrangements to determine whether units of account within the collaboration arrangement exhibit the characteristics of a vendor and customer relationship. The Company determined that the licenses transferred to Kaken in exchange for the upfront fees were representative of this type of a relationship. If a 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 performance obligations, 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. The Company evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition on a prospective basis.

Under Topic 606, the Company evaluated the terms of the Kaken Agreement and the transfer of intellectual property and manufacturing rights (the “license”) was identified as the only performance obligation as of the inception of the agreement. The Company concluded that the license for the intellectual property was distinct from its ongoing supply obligations. The Company further determined that the transaction price under the arrangement was comprised of the \$11.0 million upfront payment. The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained. As part of the Company’s evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals, each of which is uncertain at this time. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur. Future potential milestone amounts would be recognized as revenue from collaboration arrangements, if unconstrained. The remainder of the arrangement, which largely consisted of both parties incurring costs in their respective territories, provides for the reimbursement of the ongoing supply costs. These costs were representative of a collaboration arrangement outside of the scope of Topic 606 as it does not have the characteristics of a vendor and customer relationship. Reimbursable program costs are recognized proportionately with the delivery of drug substance and are accounted for as reductions to research and development expense and are excluded from the transaction price.

Under Topic 606, the entire transaction price of \$11.0 million was allocated to the license performance obligation. The license was deemed to be delivered in 2015 in connection with the execution of the Kaken Agreement and upon transfer of the underlying intellectual property the performance obligation was fully satisfied. As a result, a cumulative adjustment to reduce deferred revenue and the corresponding sublicensing costs of \$2.7 million was recorded upon the adoption of Topic 606 on January 1, 2018. As of December 31, 2018, the Company does not have a deferred revenue or deferred sublicensing costs balance related to the upfront fee on the balance sheet.

In May 2018, the Company entered into an amendment to the Kaken Agreement (as further amended, “Kaken Agreement”), pursuant to which, the Company received an upfront non-refundable fee of \$15.6 million (the “Collaboration R&D Payment”), which was initially recorded as deferred revenue, to provide the Company with research and development funds to conduct certain clinical trials. These clinical trials have a benefit to Kaken and have the characteristics of a vendor and customer relationship. The Company has accounted for these under the provisions of Topic 606. This Collaboration R&D Payment will be initially recognized using an input method over the average estimated performance period of 1.45 years in proportion to the cost incurred. Upon receipt of the Collaboration R&D Payment, on May 31, 2018, a milestone payment originally due upon the first commercial sale in Japan was removed from the Collaboration Agreement and all future royalties to the Company under the Collaboration Agreement were reduced 150 basis points.

Consequently, during the year ended December 31, 2018, the Company recognized revenue of \$5.9 million related to the Collaboration R&D Payment. As of December 31, 2018, the Company has a deferred revenue balance related to the Collaboration



R&D Payment of \$9.7 million, of which \$8.1 million, is recorded in deferred revenue, current portion on the accompanying balance sheets.

#### *Milestones*

At the inception of each arrangement that includes milestone payments (variable consideration), 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 revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company or its collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. 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 milestones and any related constraint, and if necessary, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration or other revenues and earnings in the period of adjustment.

In October 2017, the Company entered into an amendment to the Kaken Agreement, pursuant to which, the Company granted Kaken a prepayment option (the "Kaken Option") on 50% of the Initiation of Phase III milestone (the "Phase III milestone"). The Kaken Option was exercisable by Kaken within 25 business days of receipt of the BBI-4000-CL-203 study topline results. In December 2017, Kaken exercised the Kaken Option and paid the Company \$5.0 million (the "Kaken Option Payment"). Upon receipt of the non-refundable Kaken Option Payment, the Company provided Kaken the right to negotiate an exclusive license to develop, manufacture and commercialize each of the Company's other product candidates in Japan ("ROFN Agreement"). Under the ROFN Agreement, following the completion of any Initial Proof of Concept Clinical Trial ("Initial POC") for the Company's other product candidates, the Company must provide Kaken with certain information relating to the results of the clinical trial ("Initial POC Package"). The ROFN Agreement is exercisable by Kaken within 30 days of receipt of the Initial POC Package. In December 2017, the Company recognized collaboration revenue related to the Kaken Agreement of \$5.0 million, in connection with the Kaken Option. Additionally, the Company recognized sublicensing costs of \$1.0 million, which are included in general and administrative expenses.

The Kaken Agreement was further amended in March 2018 to accelerate payment of the Phase III milestone. The Phase III milestone was modified to be due upon the successful completion of the End of Phase 2 Meeting with the PMDA by Kaken on March 8, 2018, as determined by Kaken in its reasonable discretion (the "Third Milestone"). In March 2018, Kaken triggered the Third Milestone and paid the Company \$5.0 million (the "Third Milestone Payment"). Upon receipt of the non-refundable Third Milestone Payment, the ROFN Agreement was amended (the "Amended ROFN Agreement") to grant an additional option to exercise upon completion of a Subsequent Clinical Trial (first clinical trial after the Initial POC) for the Company's other product candidates. The Company has determined that the ROFN Agreement is not a material right and has not allocated transaction price to this provision. As of December 31, 2018, Kaken has not exercised the Amended ROFN Agreement. In March 2018, the Company recognized collaboration revenue related to the Kaken Agreement of \$5.0 million in connection with the Third Milestone. Additionally, the Company recognized sublicensing costs of \$1.0 million, which are included in general and administrative expenses.

#### *Royalties*

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognized 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 from any collaborative arrangement.

Under collaborative arrangements, the Company has been reimbursed for a portion of the Company's research and development expenses, including costs of drug supplies. When the research and development services are performed under a reimbursement or cost sharing model with a collaboration partner, the Company records these reimbursements as a reduction of research and development expense in the Company's statements of operations.

#### *Revenue recognition prior to adoption of Topic 606*

Prior to the adoption of Topic 606, the Company was initially recorded the \$11.0 million upfront fee as deferred revenue. This upfront fee, along with the corresponding sublicensing fees, was initially recognized over the estimated period during which the research and development plan would be conducted. Consequently, during the years ended December 31, 2017 and 2016, the Company recognized revenue of \$2.6 million and \$2.9 million, respectively. As of December 31, 2017 and 2016, the Company has a deferred revenue balance related to the upfront fee of \$3.4 million and \$6.0 million, respectively, of which \$1.7 million and \$2.9 million, respectively, is recorded in deferred revenue, current portion on the accompanying balance sheets.

Additionally, during the years ended December 31, 2017 and 2016, the Company recognized sublicensing costs of \$0.5 million and \$0.6 million, respectively, which are included in general and administrative expenses in the accompanying statements of operations. As of December 31, 2017 and 2016, the Company has \$0.7 million and \$1.2 million, respectively, in deferred sublicensing costs related to the upfront fee, of which \$0.3 million and \$0.6 million, respectively, is recorded in deferred sublicensing costs, current portion on the accompanying balance sheets.

#### ***Contingent Consideration***

Contingent consideration represents future amounts the Company may be required to pay in conjunction with business combinations. The ultimate amount of future payments is based on specified future criteria, such as the achievement of certain future development and regulatory milestones. The Company estimates the fair value of the contingent consideration related to the achievement of future development and regulatory milestones by assigning an achievement probability to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The Company evaluates its estimates of the fair value of contingent consideration on a periodic basis. Any changes in the fair value of contingent consideration are recorded in the accompanying statements of operations as general and administrative expenses. The total estimated fair value of contingent consideration was approximately \$145,000 and \$148,000 at December 31, 2018 and 2017, respectively.

#### ***Research and Development***

Research and development costs are charged to expense when incurred and consist of costs incurred for independent and collaborative research and development activities. The major components of research and development costs include formulation development, clinical studies, clinical manufacturing costs, salaries and employee benefits, toxicology studies, allocations of various overhead and occupancy costs, and licensing fees and milestone payments incurred under license agreements. Research costs typically consist of applied research, preclinical, and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis, and the transfer and scale-up of manufacturing at contract manufacturers.

#### ***Accrued Research and Development Expenses***

The Company records accruals for estimated costs of research, preclinical and clinical studies, and manufacturing development, which are a significant component of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, including CROs. The Company's contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on actual work completed in accordance with the respective agreements. In the event the Company makes advance payments, the payments are recorded as a prepaid asset and recognized as the services are performed. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services.

The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company understands the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. To date, there have been no material differences from the Company's accrued estimated expenses to the actual clinical trial expenses. However, variations in the assumptions used to estimate accruals including, but not limited to the number of patients enrolled, the rate of patient enrollment, and the actual services performed may vary from the Company's estimates, resulting in adjustments to, clinical trial expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its financial condition and results of operations.

Prepaid expenses and other current assets includes prepaid research and development costs of \$95,000 and \$12,000 as of December 31, 2018 and 2017, respectively.

#### ***Stock-Based Compensation***

Stock options granted to employees and non-employees under the Company's stock option plan are accounted for by using a fair value based method. Stock-based payments to employees, including grants of employee stock options, are measured based on their fair values at the date of grant, net of forfeitures, and are recorded on a straight-line basis over the requisite employee service period. The

fair value of stock-based payments to non-employees is estimated at each reporting period, net of forfeitures, until a measurement date is reached, and recorded over the service period on a straight-line basis.

### ***Net Loss per Common Share***

Basic and diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. When the effects are not anti-dilutive, diluted earnings per share is computed by dividing the Company's net earnings by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares.

Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the period, including stock options and warrants, using the treasury stock method, and redeemable convertible preferred stock, using the if-converted method. In computing diluted earnings per share, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted earnings per share computation in net loss periods, since their effect would be anti-dilutive.

The following table sets forth the potential common shares excluded from the calculation of net loss per common share, because their inclusion would be anti-dilutive:

	<u>2018</u>	<u>2017</u>
Redeemable convertible preferred stock (as converted into common stock)	1,256,466	1,256,466
Options to purchase common stock	376,299	285,224
Warrants to purchase common stock	55,344	55,344
Warrants to purchase redeemable convertible preferred stock (as converted into common stock)	9,005	9,005
	<u>1,697,114</u>	<u>1,606,039</u>

### ***Income Taxes***

The Company accounts for income taxes under the liability method, whereby deferred tax assets and liabilities are provided for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

Deferred tax assets, net of a valuation allowance, are recorded when management believes it is more likely than not that the tax benefits will be realized. Realization of the deferred tax assets is dependent upon generating sufficient taxable income in the future. The amount of deferred tax asset considered realizable could change in the near term if estimates of future taxable income are modified. The Company assesses its tax positions and determines whether it has any material unrecognized liabilities for uncertain tax positions expected to be taken in a tax return for open tax years (generally a period of three years from the later of each return's due date or the date filed) that remain subject to examination by the Company's major tax jurisdictions. Generally, the Company is no longer subject to income tax examinations by major taxing authorities for years before 2014.

The Company assesses its tax positions and determines whether it has any material unrecognized liabilities for uncertain tax positions. The Company records these liabilities to the extent it deems them more likely than not to be incurred. Interest and penalties related to uncertain tax positions, if any, would be classified as a component of income tax expense. The Company believes that it does not have any significant uncertain tax positions requiring recognition or measurement in the accompanying financial statements.

### ***Segment Data***

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is identifying, developing and commercializing innovative and differentiated therapeutics for the treatment of skin diseases. No revenue from sales of product has been generated since inception, and all tangible assets are held in the United States.

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**NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS**

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In November 2018, the Financial Accounting Standards Board (“FASB”) issued ASU 2018-18. ASU 2018-18 clarifies when certain transactions between collaborative arrangement participants should be accounted for under ASC 606 and incorporates unit-of-account guidance consistent with ASC 606 to aid in this determination. ASU 2018-18 is effective for public companies for annual and interim periods beginning after December 15, 2019, with early adoption permitted. ASU 2018-18 should generally be applied retrospectively to the date of initial application of Topic 606. The Company adopted this standard as of January 1, 2018 in connection with its adoption of Topic 606.

As noted above, effective January 1, 2018, the Company adopted Topic 606. Since ASU 2014-09 was issued, several additional ASUs have been issued and incorporated within Topic 606 to clarify various elements of the guidance. As part of its adoption efforts, the Company completed the assessment of its collaboration and license agreements under Topic 606. The Company adopted Topic 606 in the first quarter of 2018 using the modified retrospective method which consists of applying and recognizing the cumulative effect of Topic 606 at the date of initial application and providing certain additional disclosures as defined per Topic 606. On January 1, 2018, the Company recorded a cumulative adjustment to decrease deferred revenue, deferred sublicensing costs and accumulated deficit by approximately \$2.7 million, to reflect the impact of the adoption of Topic 606.

Below is a summary of the affected line items on the balance sheets upon adoption of Topic 606 (in thousands):

<b>Balance Sheet</b>	<b>Balance at December 31, 2017</b>	<b>Adjustments Due to Topic 606</b>	<b>Balance at January 1, 2018</b>
Deferred sublicensing costs, current portion	\$ (342)	\$ 342	\$ —
Deferred sublicensing costs, net of current portion	(342)	342	—
Deferred revenue, current	1,709	(1,709)	—
Deferred revenue, net of current portion	1,709	(1,709)	—
Accumulated deficit	\$ (59,942)	\$ 2,734	\$ (57,208)

As a result of adopting Topic 606 on January 1, 2018 under the modified retrospective method, the Company did not revise the comparative financial statements for the prior years as if Topic 606 had been effective for those periods. Below is disclosure of what the affected line items on the statement of operations would have been in the year ended December 31, 2018 under Topic 605 (in thousands):

<b>Statement of Operations</b>	<b>Year Ended December 31, 2018</b>		
	<b>As Reported</b>	<b>Balances Without Adoption Topic 606</b>	<b>Effect of Change</b>
Collaboration revenue	\$ 10,888	13,186	(2,298)
General and administrative	(6,379)	(6,724)	345

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”), which amends certain disclosure requirements over Level 1, Level 2 and Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-13, but does not anticipate it will have a material impact on its disclosures.

In January 2017, the FASB issued ASU 2017-01, “Business Combinations (Topic 805): Clarifying the Definition of a Business” (“ASU 2017-01”), which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments of ASU 2017-01 are effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years for public companies and for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019 for private companies. The Company adopted this standard as of January 1, 2018, and there was no material impact to the Company’s financial statements as a result of the adoption.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments” (“ASU 2016-15”), which will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017 for public

companies and for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019 for private companies. ASU 2016-15 will require adoption on a retrospective basis. Early adoption is permitted. The Company adopted this standard as of January 1, 2018, and there was no material impact to the Company's financial statements as a result of the adoption.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)" ("ASU 2016-02"). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018 for public companies and for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019 for private companies. Early adoption is permitted. The Company will adopt ASU 2016-02 on January 1, 2019. The Company expects to recognize a right-of-use asset and a lease liability on its balance sheet for the discounted value of future lease payments from the adoption of this ASU. As of December 31, 2018, the Company had aggregate future minimum lease payments of approximately \$0.3 million. The Company is currently evaluating the full impact that the adoption of this ASU will have on its financial statements and related disclosures.

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#### NOTE 4. ACCRUED LIABILITIES

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Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2018	2017
Accrued sublicensing fees	\$ —	\$ 1,000
Accrued compensation	569	206
Accrued note issuance costs	587	537
Accrued professional fees	1,269	968
Accrued contracted research and development services	847	745
	<u>\$ 3,272</u>	<u>\$ 3,456</u>

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#### NOTE 5. INTANGIBLE ASSETS

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In January 2015, the Company acquired certain assets and assumed certain liabilities associated with the rights to an IPR&D molecular compound in the Phase I stage of development, BBI-5000, for \$100,000 plus up to an aggregate of \$13.5 million in payments contingent upon achieving certain future development milestones.

On November 23, 2015, the Company secured the exclusive worldwide rights to a series of novel retinoic acid-related orphan nuclear receptor gamma ("RORγ") inhibitors from Orca Pharmaceuticals ("Orca") and New York University ("NYU"), for an upfront payment of \$105,000 plus up to an aggregate of \$3.4 million in payments contingent upon achieving certain future development and sales milestones.

The Company accounted for both transactions as business combinations. The asset purchase agreements meet the definition of a business pursuant to the guidance prescribed in ASC Topic 805, "Business Combinations." Accordingly, for BBI-5000 and BBI-6000, the Company capitalized the \$321,000 and \$120,000 acquisition-date fair values of these intangible assets, respectively. As of all periods presented, these assets are considered to be indefinite-lived and will not be amortized, but will be tested for impairment on an annual basis, as well as between annual tests if changes in circumstances indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives.

For BBI-5000 and BBI-6000 the Company has estimated the fair value of the contingent consideration to be \$221,000 and \$15,000, respectively, as of the acquisition date by assigning an achievement probability to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The Company evaluates its estimates of the fair value of contingent consideration on a periodic basis. Any changes in the fair value of contingent consideration are recorded as general and administrative expense.

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**NOTE 6. INCOME TAXES**

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During the years ended December 31, 2018 and 2017, the Company recorded no income tax benefits for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	<u>2018</u>	<u>2017</u>
Federal statutory income tax rate	21.00 %	34.00 %
State taxes, net of federal benefit	3.71	1.07
Research and development tax credits	8.77	6.15
Permanent differences and other	2.36	(2.14)
Change in tax rate	1.80	(46.04)
Change in deferred tax asset valuation allowance	(37.64)	6.96
Effective income tax rate	<u>— %</u>	<u>— %</u>

At December 31, approximate deferred tax assets (liabilities) resulting from timing differences between financial and tax bases related to the following items:

	<u>2018</u>	<u>2017</u>
Net operating loss carryforwards	\$ 8,918,000	\$ 7,967,000
Stock-based compensation	520,000	393,000
Research and development credit	3,207,000	2,398,000
Net book value of intangible assets	75,000	70,000
Deferred revenue	2,040,000	718,000
Other	514,000	251,000
Net deferred tax asset	<u>15,274,000</u>	<u>11,797,000</u>
Less: valuation allowance	<u>(15,274,000)</u>	<u>(11,797,000)</u>
	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2018, the Company had net operating loss carryforwards for federal income tax reporting purposes of approximately \$36.5 million, which begin to expire in 2030, and state net operating loss carryforwards of \$30.9 million, which begin to expire in 2030. As of December 31, 2018, the Company also had research and development tax credit carryforwards for federal income tax reporting purposes available of \$3.2 million, which begin to expire in 2035.

On December 22, 2017, the U.S. Tax Cuts and Jobs Acts ("Tax Act") was signed into law. The Tax Act significantly revised the U.S. corporate income tax regime by, among other changes, lowering the federal corporate tax rate from 34% to 21% effective January 1, 2018. Based on provisions of the Tax Act, the Company remeasured its deferred tax assets and liabilities to reflect the lower statutory tax rate. The Company has recorded a decrease related to deferred tax assets of \$5.1 million. However, since the Company established a valuation allowance to offset its deferred tax assets, there is no impact to its effective tax rate, as any changes to deferred taxes would be offset by the valuation allowance.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2018 and 2017. Management reevaluates the positive and negative evidence at each reporting period. The Company's valuation allowance increased by approximately \$3.5 million and decreased by approximately \$0.8 million for the years ended December 31, 2018 and 2017, respectively.

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**NOTE 7. NOTE PAYABLE**

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***Note Payable***

On February 18, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. (the "Lender") under which the Company borrowed \$7.5 million upon the execution of the Loan Agreement. The interest rate applicable to each tranche is variable based upon the greater of either (i) 9.2% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal minus 3.5%, plus (b) 9.2%; notwithstanding the above, such rate shall not exceed the permissible rates of interest on commercial loans under the laws of the State of California. Payments under the Loan Agreement were interest only until June 1, 2017, followed by equal monthly payments of principal and interest through the scheduled maturity date on September 1, 2019.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of the Company's assets, other than its intellectual property. The Company also has agreed not to pledge or otherwise encumber its intellectual property assets, except that the Company may grant non-exclusive licenses of intellectual property entered into in the ordinary course of business, and licenses approved by the Company's Board of Directors that may be exclusive in respects other than territory and may be exclusive as to territory as to discrete geographical areas outside of the United States.

The Company has paid the Lender a facility fee of \$150,000 in connection with the Loan Agreement. In addition, if the Company repays all or a portion of the loan prior to maturity, it will pay the Lender a prepayment penalty fee, based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs prior to February 19, 2017, 2% if the prepayment occurs prior to February 19, 2018, or 1% if the prepayment occurs thereafter. In addition, the Company is required to make an end of term payment of 4.5% of the sum of (i) term loan advances, plus (ii) 50% of the aggregate unfunded term loan commitments.

The Loan Agreement was amended in December 2017 (as further amended, "Loan Agreement") to provide for an additional three-month interest only period ending on March 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, the end of term payment was increased by \$30,500.

The Loan Agreement was further amended in March 2018 to provide for an additional two-month interest only period ending on June 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, a facility fee of \$25,000 was paid upon execution and the end of term payment was increased by \$25,000.

The Loan Agreement was again amended in July 2018 to provide for an additional three-month interest only period ending on October 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, a facility fee of \$25,000 was paid upon execution and the end of term payment was increased by \$25,000.

The Loan Agreement includes customary affirmative and restrictive covenants, and also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of the Lender's security interest or in the value of the collateral, and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 4% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

Under the Loan Agreement, the Company grants the Lender the right to participate in and/or designate one or more of its affiliates to participate in any subsequent financing in an amount up to \$1.0 million on the same terms, conditions and pricing afforded to other participating in such subsequent financing.

Note payable at December 31, 2018 consisted of the following (in thousands):

Face value of note payable	\$ 7,500
Accrued interest	46
Discounts on note payable related to warrants	(329)
Note payable issuance costs	<u>(1,061)</u>
	6,156
Principal payments through December 31, 2018	(2,692)
Accumulated accretion	<u>1,175</u>
Note payable	<u><u>\$ 4,639</u></u>

The following is a schedule of aggregate note payable maturities, excluding the unamortized amount related to the end of term payment, for each of the years subsequent to December 31, 2018 (in thousands):

<b>Year Ending December 31,</b>	
2019	<u>\$ 4,808</u>
	<u><u>\$ 4,808</u></u>

In connection with the Loan Agreement, the Company issued warrants to the Lender, which are exercisable for 9,005 shares of Series C redeemable convertible preferred stock at a per share exercise price of \$33.31 (the "Warrants"). The Warrants will terminate, if not earlier exercised, on February 18, 2026. The fair value of the warrants was recorded as a redeemable convertible preferred stock warrant liability upon issuance. The fair value of the warrants on the date of issuance of \$0.3 million was determined using the Black-Scholes option-pricing model. The fair value of the warrants was recorded as a debt discount upon issuance and will be amortized to interest expense over the term of the loan based on the effective interest method.

As of December 31, 2018, there were unaccrued debt discounts and issuance costs of \$0.2 million, which were recorded as a direct deduction from note payable on the accompanying balance sheets.

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**NOTE 8. LICENSEE AGREEMENTS**

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The Company enters into licensing agreements with universities and other research related entities for the exclusive right to commercially develop, produce, manufacture, use, and sell certain products and methods of use thereof (the "Inventions"). Typically, the license agreements are effective through the later of (i) the end of the term of the last-to-expire of licensor's patent rights licensed under the license agreements, or (ii) ten years after the first sale of the first licensed product if no patent has issued from the patent rights.

In April 2011, the Company executed a license agreement with the University of Manchester ("UM") for a worldwide, exclusive license to manufacture, market, sell and sublicense BBI-2000 based upon certain patents, with a field of use, limited to all dermatological indications.

In June 2012, the Company executed a license agreement with the UAB Research Foundation ("UABRF") for a worldwide, exclusive license to manufacture, market, sell and sublicense BBI-3000 based upon certain patents, with a field of use limited to all dermatological indications.

In December 2012, the Company entered into a license agreement with Bodor Laboratories, Inc. ("Bodor") for a worldwide, exclusive license to manufacture, market, sell and sublicense sofipronium bromide based upon certain patents, with a field of use, limited to the treatment of hyperhidrosis and excessive sweating.

In November 2015, the Company entered into a license agreement with NYU for a worldwide, exclusive world-wide license to manufacture, market, sell and sublicense BBI-6000, a series of novel RORy inhibitors, initially targeting the topical treatment of psoriasis.



Under the license agreements, the Company is required to make royalty payments based upon a percentage of net sales of any product developed from the Inventions.

The Company is required to make milestone payments under the license agreements upon the occurrence of certain events related to the licensed products:

<b>Milestone</b>	<b>Range</b>
Initiation of Phase I, II and/or III clinical trials in Dermatology Field	\$25,000 - \$500,000
Filings of NDA or European equivalents in Dermatology Field	\$150,000 - \$1,000,000
Receipt of NDA approval or European equivalent in Dermatology Field	\$250,000 - \$2,000,000
Receipt of NDA approval or European or Japanese equivalent Non-Dermatology Field	\$1,000,000 - \$5,000,000

As of December 31, 2018, contractual milestone payments set forth in the license agreements to which the Company was party aggregated to \$10.8 million.

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#### **NOTE 9. COMMITMENTS AND CONTINGENCIES**

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##### ***Operating Leases***

In August 2016, the Company entered into a five-year lease for office space in Boulder, Colorado that expires on October 31, 2021 (the "Boulder Lease") subject to the Company's option to renew the Boulder Lease for two additional terms of three years each. Pursuant to the Boulder Lease, the Company leased 3,038 square feet of space in a multi-suite building. Rent payments under the Boulder Lease included base rent of \$4,430 per month during the first year of the Boulder Lease with an annual increase of 3.5%, and additional monthly fees to cover the Company's share of certain facility expenses, including utilities, property taxes, insurance and maintenance, which were \$2,160 per month during the first year of the Boulder Lease.

The terms of the Boulder Lease provide for rental payments on a monthly basis on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid. Rent expense for the years ended December 31, 2018 and 2017 was \$0.1 million.

The following is a schedule of approximate future minimum rental commitments required under operating leases for years subsequent to December 31, 2018 (in thousands):

<b>Year Ending December 31,</b>	
2019	\$ 57
2020	59
2021	51
Total future minimum rental commitments	<u>\$ 167</u>

The table above excludes approximately \$0.1 million of additional rent due over the period of the operating lease to cover the Company's share of facility expenses, including utilities, property taxes, insurance and maintenance.

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#### **NOTE 10. REDEEMABLE CONVERTIBLE PREFERRED STOCK**

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As of December 31, 2018 and 2017, the Company had authorized 4,182,943 shares of redeemable convertible preferred stock, par value of \$0.01, of which 1,162,505 are designated Series A redeemable convertible preferred stock ("Preferred Stock A"), 882,216 are designated Series B redeemable convertible preferred stock ("Preferred Stock B"), 869,565 are designated Series C redeemable convertible preferred stock ("Preferred Stock C") and 1,268,657 are designated Series C-1 redeemable convertible preferred stock ("Preferred Stock C-1")

From October 2016 through October 2017, the Company issued 312,423 shares of Preferred Stock C-1 to investors at a price of \$38.82 per share for net proceeds of \$12.0 million.

In connection with the issuance of the Preferred Stock A, B, C and C-1 (the “Preferred Stock”), the Company incurred approximately \$0.5 million of issuance costs. The unaccrued discount as of December 31, 2018 and 2017 amounted to approximately \$0.1 million.

Redeemable convertible preferred stock consisted of the following (in thousands, except share data):

December 31, 2018						
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Par Value	Fair Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A	1,162,505	401,309	\$ 4	\$ 16,098	\$ 11,898	401,309
Series B	882,216	286,151	3	13,011	9,803	286,151
Series C	869,565	256,583	3	13,018	11,418	256,583
Series C-1	1,268,657	312,423	3	16,163	13,866	312,423
	<u>4,182,943</u>	<u>1,256,466</u>	<u>\$ 13</u>	<u>\$ 58,290</u>	<u>\$ 46,985</u>	<u>1,256,466</u>

  

December 31, 2017						
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Par Value	Fair Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A	1,162,505	401,309	\$ 4	\$ 14,689	\$ 11,017	401,309
Series B	882,216	286,151	3	11,305	9,077	286,151
Series C	869,565	256,583	3	11,938	10,571	256,583
Series C-1	1,268,657	312,423	3	14,422	12,828	312,423
	<u>4,182,943</u>	<u>1,256,466</u>	<u>\$ 13</u>	<u>\$ 52,354</u>	<u>\$ 43,493</u>	<u>1,256,466</u>

The rights, preferences and privileges of the Preferred Stock are as follows:

#### **Dividends**

The Company recognizes certain dividend rights for the holders of the Preferred Stock, in that these holders will receive preference to any declaration or payment of dividends at the rate of 8% of the original issue price of \$15.45 of Preferred Stock A, \$23.58 of Preferred Stock B, \$33.31 of Preferred Stock C, and \$38.82 of Preferred Stock C-1 per share per annum, compounded annually, on each outstanding share. Holders of Preferred Stock A, B, C and C-1 rank pari passu with respect to the payment of accrued dividends. Accrued dividends at December 31, 2018 amounted to \$5.7 million (\$14.20 per share), \$3.1 million (\$10.68 per share), \$2.9 million (\$11.18 per share), and \$1.7 million (\$5.56 per share) on Preferred Stock A, B, C and C-1, respectively. Accrued dividends at December 31, 2017 amounted to \$4.8 million (\$12.00 per share), \$2.3 million (\$8.14 per share), \$2.0 million (\$7.89 per share), and \$0.7 million (\$2.24 per share) on Preferred Stock A, B, C and C-1, respectively. Accrued dividends are included as a component of redeemable convertible preferred stock in the accompanying balance sheets.

#### **Liquidation Preference**

Preferred Stock carries certain liquidation rights upon the liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary (including a change in control), whereas before any distribution or payment shall be made to the holders of any common stock, the holders of the Preferred Stock shall be entitled to be paid an amount equal to the original purchase price plus any accrued but unpaid dividends out of the assets of the Company legally available for distribution for each share. If the assets of the Company available for distribution upon liquidation are not sufficient to pay the preferred stock preference amount, the assets will be distributed ratably among the holders of the Preferred Stock in proportion to the full amount of the preference amount such holder is otherwise entitled to receive.

Any proceeds remaining after the distribution of the preference amount shall be distributed pro rata to the holders of the Preferred Stock (on as-if-converted to common stock basis) and the holders of common stock.

#### **Conversion**

Preferred Stock may be converted into common stock at the initial conversion ratio of 1:1, which ratio shall be altered in accordance with stock dividends, splits, combinations and other similar events, including the sale of additional shares of common or preferred

stock at an effective price per common share lower than the conversion price then in effect. Each share of the Preferred Stock will automatically convert into shares of common stock, at the applicable conversion ratio of each series of redeemable convertible preferred stock then in effect, upon (i) a qualified public offering with net proceeds of not less than \$30 million and a price of not less than \$166.67 per share, subject to appropriate adjustment for any stock dividend, stock split, combination or other similar recapitalization, or (ii) the date specified by written consent or agreement of the holders of at least two-thirds of the then outstanding shares of Preferred Stock voting together as a single class on an as-if-converted to common stock basis.

#### **Redemption**

At any time after July 16, 2021, the holders of the Company's Preferred Stock will have the right to require the Company to redeem all or a portion of their shares for cash at a redemption price equal to the greater of: (i) the purchase price of such shares plus all accrued and unpaid dividends thereon, or the (ii) fair market value of the shares.

#### **Voting Rights**

The holders of Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Holders of Preferred Stock have the right to vote the number of shares equal to the number of shares of common stock into which such Preferred Stock could convert on the record date for determination of stockholders entitled to vote. The holders of the majority of Preferred Stock, voting separately as a single class, are entitled to elect two directors of the Company.

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#### **NOTE 11. STOCK-BASED COMPENSATION**

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The Company's 2009 Equity Incentive Plan, as amended and restated (the "2009 Plan"), provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Board of Directors and consultants of the Company. At December 31, 2018, the total shares authorized under the 2009 Plan were 991,796 shares. The Board of Directors or a designated committee of the Board of Directors is responsible for the administration of the 2009 Plan and determines the term, exercise price, and vesting terms of each option. Under the terms of existing awards, all stock option grants expire ten years from grant date.

A summary of all stock option activity under the 2009 Plan is presented below:

<b>Outstanding Options</b>	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Total Intrinsic Value</b>	<b>Weighted Average Remaining Contractual Life (In Years)</b>
Outstanding at December 31, 2017	467,449	\$ 11.33	\$ 2,511,589	7.74
Granted	267,869	\$ 16.45		
Exercised	(3,739)	\$ 12.17		
Forfeited	(34,737)	\$ 12.72		
Outstanding at December 31, 2018	696,842	\$ 13.21	\$ 2,265,118	7.96
Options vested and exercisable at December 31, 2018	376,299	\$ 10.86	\$ 2,103,832	6.51
Options vested at December 31, 2018 and expected to vest	674,437	\$ 13.12	\$ 2,253,829	7.91

At December 31, 2018 and 2017, a total of 185,746 shares and 144 shares, respectively, were available for grant under the 2009 Plan. The total estimated grant date fair value of stock options vested during the years ended December 31, 2018 and 2017 was \$0.8 million and \$0.9 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2018 and 2017 amounted to \$0.1 million.

Total stock-based compensation expense related to stock options granted under the 2009 Plan was allocated as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Research and development	\$ 340	\$ 343
General and administrative	371	538
Total stock-based compensation expense	<u>\$ 711</u>	<u>\$ 881</u>

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock-based awards. The determination of the fair value of stock-based awards on the date of grant using an option-pricing model is affected by the value of the Company's stock price, as well as assumptions regarding subjective variables. These variables include expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends.

The Company estimates the "simplified method" in accordance with Staff Accounting Bulletin ("SAB") No. 107, "Share-Based Payment," and SAB No. 110, "Simplified Method for Plain Vanilla Share Options," to develop the expected term of stock option awards that qualify as "plain-vanilla" options. Under this approach, the expected term of the option grant is presumed to be the midpoint between the vesting date and the contractual end of the option grant. The expected term of all other stock options granted is based on the Company's historical share option exercise experience, which approximates the midpoint between the vesting date and the contractual end of the option grant. The Company estimates volatility of the common stock by using the average share fluctuations of companies similar in size, operations, and life cycle. The risk-free interest rates used in the valuation model are based on U.S. Treasury issues with remaining terms similar to the expected term on the options. The Company does not anticipate paying any dividends in the foreseeable future and therefore used an expected dividend yield of zero.

Management has estimated the forfeiture rate at 7% based on past experience, forfeiture rates and the individuals receiving the options. The Company will monitor actual forfeiture experience and will periodically update forfeiture estimates based on actual experience. As of December 31, 2018, there was total unrecognized compensation expense of approximately \$3.7 million, which is expected to be recognized over a period of approximately 3.96 years.

#### Stock Options Granted to Employees

During the years ended December 31, 2018 and 2017, the Company granted 252,681 stock options and 37,452 stock options, respectively, to employees and non-employee directors to purchase shares of common stock with a weighted-average grant date fair value of \$12.05 and \$11.64 per share, respectively, and a weighted-average exercise price of \$16.45 and \$15.79 per share, respectively.

The assumptions used to calculate the fair value of stock options granted to employees and non-employee directors under the 2009 Plan are as follows, presented on a weighted average basis:

	2018	2017
Expected term (in years)	6.1	6.1
Expected volatility	85.43 %	88.19 %
Risk free interest rate	2.77 %	2.16 %
Expected dividend yield	— %	— %

The stock-based compensation expense related to employee stock options was approximately \$0.6 million for the years ended December 31, 2018 and 2017.

#### Stock Options Granted to Non-employees

During the years ended December 31, 2018 and 2017, the Company granted 15,188 stock options and 8,629 stock options, respectively, to persons other than employees and non-employee members of the Company's Board of Directors with a weighted-average exercise price of \$16.45 and \$15.47 per share, respectively.

The assumptions used to calculate the fair value of stock options granted to non-employees under the 2009 Plan are as follows, presented on a weighted average basis:

	<u>2018</u>	<u>2017</u>
Expected term (in years)	9.96	9.85
Expected volatility	86.17 %	84.39 %
Risk free interest rate	2.69 %	2.35 %
Expected dividend yield	— %	— %

The stock-based compensation expense related to non-employee stock options was approximately \$0.1 million and \$0.2 million for the years ended December 31, 2018 and 2017, respectively.

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## NOTE 12. STOCKHOLDERS' DEFICIT

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### *Common Stock*

As of December 31, 2018, the Company had authorized 8,000,000 shares of common stock, par value \$0.01 per share.

The Company has reserved authorized shares of common stock, on an as-converted basis, for future issuance at December 31, 2018 as follows:

	<u>2018</u>
Conversion of Preferred Stock A	401,309
Conversion of Preferred Stock B	286,151
Conversion of Preferred Stock C	256,583
Conversion of Preferred Stock C-1	312,423
Preferred Stock C warrants issued with note payable	9,005
Common stock warrants	55,344
Common stock options outstanding	696,842
Options available for grant under the 2009 Plan	185,746
	<u>2,203,403</u>

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## NOTE 13. SUBSEQUENT EVENTS

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### *Bridge Financing—Convertible Promissory Notes with Warrants*

In March 2019, the Company initiated a convertible promissory notes offering pursuant to which the Company issued unsecured convertible promissory notes (the "Prom Notes"), bearing interest at 12.00% with a maturity of one year and convertible into shares of Series C-1 redeemable convertible preferred stock or the most senior preferred equity outstanding at the time of conversion at the option of the holder at a conversion price of \$31.05 per share. In addition, the Prom Notes were automatically convertible upon closing of a qualified financing of at least \$15.0 million before maturity at a conversion price equal to 80% of the effective price per share paid in the qualified financing, but not to exceed \$38.82 per share. Through August 31, 2019, the Company had raised an aggregate principal amount of \$7.4 million in Prom Notes. On August 31, 2019, prior to the Merger, the Prom Notes and related accrued interest converted into 1,069,740 shares of common stock at a conversion price of \$7.54 per share.

The Prom Notes also provided for the issuance of warrants at 50% coverage, to acquire 490,683 shares of common stock. The warrants are exercisable for a term of five years at an exercise price of \$10.36. The Company evaluated the various financial instruments under ASC 480 and ASC 815 and determined the warrants required fair value accounting. The fair value of the warrants was recorded as a warrant liability upon issuance. The fair value of the warrants on the dates of issuance of \$1.5 million was determined with the assistance of a third-party valuation firm. The fair value of the warrants was recorded as a debt discount upon issuance and was amortized to interest expense over the term of the Prom Notes based on the effective interest method.

***Merger of Brickell Biotech, Inc. and Vical Incorporated***

On August 31, 2019, the Company completed a recapitalization in accordance with the terms of the Merger Agreement, by and among Vical, Merger Sub, and the Company, which is described in Note 1.

***Note Payable***

On September 3, 2019, the Company repaid the remaining outstanding loan balance under the Loan Agreement, which consisted of the remaining outstanding loan balance of \$2.6 million and an associated accrued interest and aggregate end-of-term payment of \$0.6 million, and the Loan Agreement was terminated. At the effective time of the Merger, the warrant liability was reclassified to equity in the condensed consolidated balance sheet.

***Bodor License Agreement***

On October 23, 2019, Bodor notified the Company of its purported termination of the license agreement it entered into with Bodor, dated December 15, 2012, as amended by Amendment No. 1 to the License Agreement, effective as of October 21, 2013, and Amendment No. 2 to the License Agreement, effective as of March 31, 2015 (the "License Agreement"). In connection with this attempt, on October 23, 2019, Bodor and Dr. Nicholas S. Bodor (collectively, the "Bodor Plaintiffs") filed a complaint (the "Bodor Complaint") against the Company in the United States District Court for the Southern District of Florida. The Bodor Complaint alleges damages incurred by the Bodor Plaintiffs in connection with its alleged material breach of the License Agreement and requests a declaratory judgment that the attempted termination of the License Agreement by Bodor be permitted. As required by the License Agreement, the Company initiated an arbitration proceeding and then subsequently a mediation with the Bodor Plaintiffs to resolve the dispute. In the Company's arbitration demand, it countersued the Bodor Plaintiffs for damages caused by them to the Company, both under contract and due to their tortious interference with the Company's business relations. The Company asked the district court to dismiss or stay the Bodor Complaint. The judge administratively closed the case pending arbitration. The Company believes that the claims and assertions made by the Bodor Plaintiffs are in substance without merit. Following an unsuccessful mediation, the Company and the Bodor Plaintiffs commenced arbitration. Pending successful resolution of this dispute and obtaining substantial additional funding, the Company intends to conserve its resources. The advancement of the Phase 3 clinical trials for sofpironium bromide have been negatively impacted by these developments, and the Company will require substantial additional funds. The Company has taken, and expects to continue to take, actions to reduce its cash spend, including delaying the start of the clinical trials and/or staff reductions. In December 2019, an estimated loss contingency of \$1.0 million was recorded for this matter, and the Company will continue to evaluate the adequacy of this estimate as the matter develops.