CONCERT PHARMACEUTICALS, INC.
Form 10-Q
May 02, 2019
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 10-Q

_____

(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2019
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number 001-36310

_____

CONCERT PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

_____

Delaware (State or other jurisdiction of incorporation or organization)	20-4839882 (I.R.S. Employer Identification No.)
65 Hayden Avenue, Suite 3000N Lexington, Massachusetts (Address of principal executive offices)	02421 (Zip Code)

(781) 860-0045
(Registrant's telephone number, including area code)

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CNCE	The NASDAQ Global Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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. x

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

The number of shares outstanding of the registrant's common stock as of April 30, 2019: 23,796,288

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

CONCERT PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(Amounts in thousands, except share and per share data)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$60,262	$ 17,770
Investments, available for sale	93,545	135,544
Marketable equity securities	5,226	7,525
Interest receivable	382	556
Accounts receivable	11	15
Contract asset (Note 8)	—	16,000
Prepaid expenses and other current assets	2,358	2,739
Total current assets	161,784	180,149
Property and equipment, net	8,640	8,919
Restricted cash	1,157	1,157
Other assets	22	—
Income taxes receivable	2,358	2,322
Operating lease right-of-use assets, long-term (Note 11)	9,430	—
Total assets	$183,391	$ 192,547
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$1,613	$ 1,277
Accrued expenses and other liabilities	4,720	5,669
Income taxes payable	—	390
Deferred revenue, current portion	1,413	1,413
Lease liability, current portion (Note 11)	169	—
Total current liabilities	7,915	8,749
Deferred revenue, net of current portion	9,120	9,120
Deferred lease incentive, net of current portion	—	4,088
Deferred rent, net of current portion	—	2,850
Lease liability, net of current portion (Note 11)	16,558	—
Total liabilities	$33,593	$ 24,807
Commitments (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized; no shares issued and outstanding in 2019 and 2018, respectively	—	—
Common stock, $0.001 par value per share; 100,000,000 shares authorized; 23,946,357 and 23,518,690 shares issued and 23,756,801 and 23,437,587 outstanding in 2019 and 2018, respectively	23	23
Additional paid-in capital	288,156	284,369
Accumulated other comprehensive loss	(40)	(137)
Accumulated deficit	(138,341)	(116,515)
Total stockholders' equity	149,798	167,740
Total liabilities and stockholders' equity	$183,391	$ 192,547

See accompanying notes.

CONCERT PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(Amounts in thousands, except per share data)

	Three Months Ended March 31,	
	2019	2018
Revenue:		
License and research and development revenue	$1,005	$10,479
Operating expenses:		
Research and development	15,790	8,656
General and administrative	5,609	5,630
Total operating expenses	21,399	14,286
Loss from operations	(20,394)	(3,807)
Investment income	867	640
Unrealized loss on marketable equity securities	(2,299)	(1,296)
Net loss	$(21,826)	$(4,463)
Other comprehensive loss:		
Unrealized gain (loss) on investments, available for sale	97	(75)
Comprehensive loss	$(21,729)	$(4,538)
Net loss per share applicable to common stockholders - basic and diluted	$(0.93)	$(0.19)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	23,508	23,223

See accompanying notes.

CONCERT PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (UNAUDITED)

	Three Months Ended March 31, 2019						
	Common Stock			Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Issued	In Treasury	Amount				
	(in thousands)						
Balance at December 31, 2018	23,519	81	$ 23	$284,369	$ (137)	$ (116,515)	$ 167,740
Exercise of stock options	154	47	—	805	—	—	805
Release of restricted stock units	202	61	—	(741)	—	—	(741)
Unrealized gain on short-term investments	—	—	—	—	97	—	97
Stock-based compensation expense	—	—	—	2,929	—	—	2,929
Exercise of stock warrants	71	—	—	1,000	—	—	1,000
Offering expenses incurred	—	—	—	(206)	—	—	(206)
Net loss	—	—	—	—	—	(21,826)	(21,826)
Balance at March 31, 2019	23,946	189	$ 23	$288,156	$ (40)	$ (138,341)	$ 149,798

	Three Months Ended March 31, 2018						
	Common Stock			Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Issued	In Treasury	Amount				
	(in thousands)						
Balance at December 31, 2017	23,148	8	$ 23	$273,059	$ (407)	$ (76,243)	$ 196,432
Exercise of stock options	145	17	—	658	—	—	658
Release of restricted stock units	174	53	—	(1,206)	—	—	(1,206)
Unrealized loss on short-term investments	—	—	—	—	(75)	—	(75)
Stock-based compensation expense	—	—	—	3,299	—	—	3,299
Adoption of ASC 606 as of January 1, 2018	—	—	—	—	—	15,752	15,752
Net loss	—	—	—	—	—	(4,463)	(4,463)
Balance at March 31, 2018	23,467	78	$ 23	$275,810	$ (482)	$ (64,954)	$ 210,397

CONCERT PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(Amounts in thousands)

	Three Months Ended March 31,	
	2019	2018
Operating activities		
Net loss	$(21,826)	$(4,463)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	444	253
Stock-based compensation expense	2,929	3,299
Accretion of premiums and discounts on investments	(294)	(53)
Amortization of deferred lease incentive	—	(196)
Non-cash license consideration (Note 8)	—	(10,452)
Unrealized loss on marketable equity securities	2,299	1,296
Loss on disposal of asset	4	—
Non-cash lease expense (Note 11)	49	—
Changes in operating assets and liabilities:		
Accounts receivable	4	6
Interest receivable	174	48
Prepaid expenses and other current assets	381	(811)
Contract asset	16,000	—
Other assets	(23)	10
Accounts payable	479	236
Accrued expenses and other liabilities	(1,388)	(2,270)
Income taxes receivable	(36)	—
Income taxes payable	(390)	(50)
Deferred rent	—	678
Deferred revenue	—	(16)
Operating lease liability (Note 11)	(144)	—
Net cash used in operating activities	(1,338)	(12,485)
Investing activities		
Purchases of property and equipment	(315)	(325)
Purchases of investments	(13,331)	(7,941)
Maturities of investments	55,721	28,114
Net cash provided by investing activities	42,075	19,848
Financing activities		
Proceeds from exercise of stock options	805	669
Proceeds from exercise of warrants	1,000	—
Payment of public offering costs	(50)	—
Net cash provided by financing activities	1,755	669
Net increase in cash and cash equivalents and restricted cash	42,492	8,032
Cash, cash equivalents and restricted cash at beginning of period	18,927	29,222
Cash, cash equivalents and restricted cash at end of period	$61,419	$37,254
Supplemental cash flow information:		
Cash paid for income taxes	$425	$50
Purchases of property and equipment unpaid at period end	$16	$706
Public offering costs unpaid at period end	$156	$—
Cash paid included in measurement of lease liabilities	$694	$—

Tenant improvements paid by landlord	$—	$1,414

See accompanying notes.

CONCERT PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. Nature of Business

Concert Pharmaceuticals, Inc., or Concert or the Company, was incorporated on April 12, 2006 as a Delaware corporation with operations based in Lexington, Massachusetts. The Company is a clinical stage biopharmaceutical company that applies its extensive knowledge of deuterium chemistry to discover and develop novel small molecule drugs. The Company's approach starts with previously studied compounds, including approved drugs, that the Company believes can be improved with deuterium substitution to provide better pharmacokinetic or metabolic properties, enhancing clinical safety, tolerability or efficacy. The Company believes this approach may enable drug discovery and clinical development that is more efficient and less expensive than conventional small molecule drug research and development. The Company's pipeline includes multiple clinical-stage candidates and a number of preclinical compounds that it is currently assessing.

The Company had cash and cash equivalents and investments of $153.8 million at March 31, 2019. The Company believes that its cash and cash equivalents and investments at March 31, 2019 will be sufficient to allow the Company to fund its current operating plan for at least the next twelve months. The Company may pursue additional cash resources through public or private financings and by establishing collaborations with or licensing its technology to other companies and through other arrangements.

Since its inception, the Company has generated an accumulated deficit of $138.3 million through March 31, 2019. The Company's operating results may fluctuate significantly from year to year, depending on the timing and magnitude of clinical trial and other development activities under its current development programs. Substantially all the Company's net losses have resulted from costs incurred in connection with its research and development programs and from general and administrative costs associated with its operations. The Company expects to continue to incur significant expenses and increasing operating losses for at least the next several years.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, risks of failure or unsatisfactory results of nonclinical studies and clinical trials, the need to obtain additional financing to fund the future development of its pipeline, the need to obtain marketing approval for its product candidates, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations and ability to transition from pilot-scale manufacturing to large-scale production of products.

Unless otherwise indicated, all amounts are in thousands except share and per share amounts.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the condensed consolidated financial statements have been included. Interim results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2019 or any other future period.

The accompanying condensed consolidated financial statements reflect the accounts of Concert and its subsidiaries. All intercompany transactions between the Company and its subsidiaries have been eliminated. Management has determined that the Company operates in one segment: the development of pharmaceutical products on its own behalf

or in collaboration with others. The information included in this quarterly report on Form 10-Q should be read in conjunction with the Company's consolidated financial statements and the accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on February 28, 2019.

Use of Estimates and Summary of Significant Accounting Policies

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue, expenses and the disclosure of contingent assets and liabilities and the Company's ability to continue as a going concern. In preparing the consolidated financial statements, management used estimates in the following areas, among others: revenue recognition; lease accounting; income tax expense; stock-based compensation expense; accrued expenses; and the

CONCERT PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

evaluation of the existence of conditions and events that raise substantial doubt regarding the Company's ability to continue as a going concern. Actual results could differ from those estimates.

With the exception of the adoption of Accounting Standards Update, or ASU, 2016-02 during the three months ended March 31, 2019 discussed in Note 11, there have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-02, Leases, or Topic 842. ASU 2016-02 requires lessees to recognize assets and liabilities on the balance sheet for the rights and obligations created by leases. On January 1, 2019, the Company adopted ASU 2016-02 and all related amendments. For discussion regarding the impact of this accounting pronouncement, refer to Note 11 appearing elsewhere in this quarterly report on Form 10-Q.

In June 2018, the FASB issued ASU 2018-07, or Topic 718, Improvements to Nonemployee Share-Based Payment Accounting, that expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 provides that an entity should apply the requirements of Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The Company adopted this new standard effective January 1, 2019, and it did not have a material effect on the consolidated financial statements and related disclosures.

In August 2018, the Securities and Exchange Commission issued Release No. 33-10532 that amends and clarifies certain financial reporting requirements. The principal change to the Company's financial reporting is the inclusion of the annual disclosure requirement of changes in stockholders' equity in Rule 3-04 of Regulation S-X to interim periods. The Company has adopted this new rule beginning with its financial reporting for the quarter ended March 31, 2019.

Pending Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses, or Topic 326, Measurement of Credit Losses on Financial Instruments. The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 will become effective for the Company for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact ASU 2016-13 will have on its financial statements and related disclosures.

3. Fair Value Measurements

The Company has certain financial assets and liabilities that are recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements:

- Level 1—quoted prices for identical instruments in active markets;
- Level 2—quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets; and
- Level 3—valuations derived from valuation techniques in which one or more significant value drivers are unobservable.

The tables below present information about the Company's financial assets and liabilities that are measured and carried at fair value as of March 31, 2019 and December 31, 2018 (in thousands) and indicate the level within the fair value hierarchy where each measurement is classified.

CONCERT PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

	Level 1	Level 2	Level 3	Total
March 31, 2019				
Cash equivalents:				
Money market funds	$25,775	$—	$	—$25,775
Government agency securities	999	20,222	—	21,221
U.S. Treasury obligations	—	2,498	—	2,498
Investments, available for sale:				
U.S. Treasury obligations	32,181	—	—	32,181
Government agency securities	46,213	15,151	—	61,364
Marketable equity securities:				
Corporate equity securities (Note 8)	5,226	—	—	5,226
Total	$110,394	$37,871	$	—$148,265

	Level 1	Level 2	Level 3	Total
December 31, 2018				
Cash equivalents:				
Money market funds	$7,643	$—	$	—$7,643
U.S. Treasury obligations	1,748	—	—	1,748
Investments, available for sale:				
U.S. Treasury obligations	34,103	746	—	34,849
Government agency securities	64,733	35,962	—	100,695
Marketable equity securities:				
Corporate equity securities (Note 8)	7,525	—	—	7,525
Total	$115,752	$36,708	$	—$152,460

4. Cash, Cash Equivalents, Investments and Marketable Equity Securities

Cash equivalents include all highly liquid investments maturing within 90 days from the date of purchase. Investments consist of securities with original maturities greater than 90 days when purchased. The Company classifies these investments as available-for-sale and records them at fair value in the accompanying consolidated balance sheets. In accordance with ASU 2016-01, unrealized gains or losses from equity securities are included in net income. Unrealized gains or losses from other investments, including debt securities, are included in accumulated other comprehensive income (loss). Premiums or discounts from par value are amortized to investment income over the life of the underlying investment.

Cash, cash equivalents, available for sale investments, and marketable equity securities included the following at March 31, 2019 and December 31, 2018:

CONCERT PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

	Average maturity	Amortized cost	Unrealized gains	Unrealized losses	Fair value
March 31, 2019					
Cash		$ 10,768	$ —	$ —	$ 10,768
Money market funds		25,775	—	—	25,775
Government agency securities	20 days	21,221	—	—	21,221
U.S. Treasury obligations	30 days	2,498	—	—	2,498
Cash and cash equivalents		$ 60,262	$ —	$ —	$ 60,262
U.S. Treasury obligations	79 days	32,180	4	(3)	32,181
Government agency securities	139 days	61,329	36	(1)	61,364
Investments, available for sale		$ 93,509	$ 40	$ (4)	$ 93,545

March 31, 2019	Acquisition value	Unrealized gains	Unrealized losses	Fair value
Marketable equity securities (Note 8)	$ 10,451	$ —	$ (5,225)	$ 5,226

	Average maturity	Amortized cost	Unrealized gains	Unrealized losses	Fair value
December 31, 2018					
Cash		$ 8,379	$ —	$ —	$ 8,379
Money market funds		7,643	—	—	7,643
U.S. Treasury obligations	31 days	1,748	—	—	1,748
Cash and cash equivalents		$ 17,770	$ —	$ —	$ 17,770
U.S. Treasury obligations	151 days	$ 34,856	$ 2	$ (9)	$ 34,849
Government agency securities	153 days	100,748	7	(60)	100,695
Investments, available for sale		$ 135,604	$ 9	$ (69)	$ 135,544

December 31, 2018	Acquisition value	Unrealized gains	Unrealized losses	Fair value
Marketable equity securities (Note 8)	$ 10,451	$ —	$ (2,926)	$ 7,525

Although available to be sold to meet operating needs or otherwise (and therefore classified as current assets), securities are generally held through maturity. The cost of securities sold is determined based on the specific identification method for purposes of recording realized gains and losses. During 2019 and 2018, there were no realized gains or losses on sales of investments, and no investments were adjusted other than for temporary declines in fair value.

5. Restricted Cash

Restricted cash as of March 31, 2019 and 2018 is held as collateral for stand-by letters of credit issued by the Company to its landlords in connection with the current and previous leases of the Company's Lexington, Massachusetts facilities.

Cash, cash equivalents and restricted cash consisted of the following:

	March 31,	March 31,

	2019	2018
Cash and cash equivalents	$60,262	$35,697
Restricted cash	1,157	1,557
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$61,419	$37,254

CONCERT PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

6. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following:

	March 31, 2019	December 31, 2018
Accrued professional fees and other	$ 793	$ 672
Employee compensation and benefits	1,543	3,067
Research and development expenses	2,384	1,476
Deferred lease incentive, current portion	—	454
	$ 4,720	$ 5,669

7. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company’s ability to use its operating loss carryforwards and tax credits to offset future taxable income is subject to restrictions under Sections 382 and 383 of the United States Internal Revenue Code (the “Internal Revenue Code”). Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code. Such changes would limit the Company’s use of its operating loss carryforwards and tax credits. In such a situation, the Company may be required to pay income taxes, even though significant operating loss carryforwards and tax credits exist.

The Company records a provision or benefit for income taxes on ordinary pre-tax income or loss based on its estimated effective tax rate for the year. As of March 31, 2019, the Company forecasts an ordinary pre-tax loss for the year ended December 31, 2019 and, since it maintains a full valuation allowance on its deferred tax assets, the Company did not record an income tax benefit for the three months ended March 31, 2019.

8. Revenue

The Company's revenue is generated through collaborative licensing agreements, patent assignments, and sales of intellectual property. The Company generates its revenue through one segment and the revenue recognized under each of the Company's arrangements during the current and prior period is described below.

On January 1, 2018, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) 2014-19, Revenue from Contracts with Customers ("ASC 606" or "the new revenue standard"). The Company adopted ASC 606 using the modified retrospective approach. For detailed information regarding the adoption of ASC 606, the impact on its consolidated financial statements and its collaboration arrangements, see Note 2 and Note 12 to the accompanying consolidated financial statements appearing in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2019.

Contract Assets

The Company did not have a contract asset as of March 31, 2019 as compared to $16.0 million as of December 31, 2018. The decrease in the contract asset balance is the result of the receipt of the Vertex indemnification payment previously held in escrow in the amount of $16.0 million.

Contract Liabilities

As of March 31, 2019 and December 31, 2018, the Company had $10.5 million, in contract liabilities related to unsatisfied performance obligations as well as variable consideration paid in advance but currently constrained from recognition.

CONCERT PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

The contract liabilities consist of the following deferred revenue:

- $7.8 million related to our collaboration with Celgene, $1.4 million of which is attributable to the CTP-730 program and is currently expected to be recognized as revenue in the next twelve months as we satisfy our remaining research and development activities pursuant to mutually agreed upon development plans, and $6.4 million of which is attributable to two additional license programs that we will not recognize as revenue until Celgene exercises its rights with respect to those programs, or at such time that Celgene's rights lapse, as detailed in Note 12 to the accompanying consolidated financial statements appearing in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2019; and
- $2.8 million related to a payment received from GlaxoSmithKline, or GSK, that we will not recognize as revenue until all repayment obligations lapse.

Revenue Arrangements

Vertex

On March 3, 2017, the Company and Vertex Pharmaceuticals, Inc. ("Vertex") entered into an Asset Purchase Agreement pursuant to which, subject to the satisfaction or waiver of the conditions therein, the Company sold and assigned to Vertex, CTP-656, a deuterated analog of ivacaftor now known as VX-561, and other cystic fibrosis assets of the Company. On July 25, 2017, the Closing Date, the transaction contemplated by the Asset Purchase Agreement closed and Vertex paid the Company $160 million in cash consideration. In addition, Vertex has agreed to pay the Company an aggregate of up to $90 million upon the achievement of certain milestone events. In February 2019, the $16.0 million initially held in escrow was released to the Company.

As of December 31, 2018, the Vertex indemnification variable consideration represented a contract asset to be released from escrow 18 months following the Closing Date and was classified as a current asset in the accompanying consolidated balance sheet. In February 2019, the $16.0 million initially held in escrow was released to the Company. Additionally, the variable consideration related to the regulatory milestone payments are fully constrained due to the uncertainty associated to the achievement of the respective milestones. Accordingly, no contract asset was recorded as of March 31, 2019.

Processa

On October 4, 2017, the Company entered into a License and Option Agreement, or the Option, with Promet Therapeutics, LLC, or Promet, pursuant to which the Company granted Promet an option to obtain an exclusive license to CTP-499, a deuterated analog of 1-(S)-5-hydroxyhexyl-3,7-dimethylxanthine, or HDX, an active metabolite of pentoxifylline, provided certain conditions were met. On October 5, 2017, Promet closed an asset purchase agreement with Heatwurx, Inc., a public company, creating Processa Pharmaceuticals, Inc. ("Processa").

On March 21, 2018, the Company entered into an Amendment to the Option, or Amendment, and a Securities Purchase Agreement, or Securities Agreement, both with Promet and Processa. Pursuant to the Amendment, the Company granted Promet, who then assigned to Processa, an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize CTP-499, now known as PCS-499. Upon transfer of the license and as consideration for the license, the Company received 2,090,301 shares of common stock of Processa, representing approximately 5.4% of the common stock outstanding.

The Company is also eligible to receive royalties on worldwide net sales.

The Amendment contained one performance obligation: an exclusive, worldwide, royalty-bearing license to develop, commercialize and sublicense CTP-499. The Company determined that the transaction price was $10.5 million, which was based on the fair value of the non-cash consideration received on March 19, 2018, which consisted of 2,090,301 shares of publicly traded common stock of Processa. The transaction price of $10.5 million was allocated to the single performance obligation. The performance obligation was considered satisfied at contract inception as the exclusive license transferred control to the customer at this point in time. Accordingly, revenue of $10.5 million was recognized during the first quarter of 2018.

Subsequent changes to the fair value of the underlying securities are recognized as unrealized gains or losses on marketable equity securities within the condensed consolidated statement of operations and comprehensive loss.

CONCERT PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

The Amendment contains consideration that is variable based on royalties upon the customer's commercial success with the licensed product. The consideration related to royalty payments is considered variable consideration that is fully constrained in accordance with the royalty recognition constraint. The variable consideration related to royalties will be recognized in the period the products are sold by Processa and the Company has a present right to payment.

For the three months ended March 31, 2019, the Company recognized $1 thousand in revenue related to intellectual property cost reimbursements. For the three months ended March 31, 2018, the Company recognized $10.5 million in revenue related to the transfer of the license.

Cipla

The Company entered into a License Agreement, or the Agreement, on January 16, 2019, or the Closing Date, with Cipla Technologies LLC, or Cipla, pursuant to which the Company granted Cipla an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize CTP-354, a novel $GABA_A$ receptor subtype-selective modulator. Upon transfer of the license and as consideration for the license, the Company received an upfront payment of $1.0 million.

The Agreement also provides Cipla the option to purchase the Company’s existing inventory held as of the Effective Date valued in aggregate at $0.3 million. Additionally, upon the achievement of certain milestone events, Cipla has agreed to pay the Company an aggregate of up to $57.0 million. The first milestone payment the Company may be entitled to receive is $3.0 million related to the U.S. Food & Drug Administration’s, or the FDA, acceptance of the first IND of the first CTP-354 product.

Furthermore, the Company is eligible to receive royalties on worldwide net sales of future product sales at defined percentages ranging from the mid-single to high-single digits.

The Agreement contained one performance obligation: an exclusive, worldwide, royalty-bearing license to develop, manufacture, commercialize and sublicense CTP-354, referred to as the Transfer of License Performance Obligation. The Company concluded the option to purchase existing inventory did not provide Cipla a material right, and as such, was treated as a separate contract. The transaction price was determined to be $1.0 million, based on the upfront consideration received as of the Closing Date.

As of the Closing Date, the Transfer of License Performance Obligation was satisfied as the control of CTP-354 transferred to Cipla, the customer. As a result, the full transaction price was recognized as revenue on the Closing Date. The sale of existing inventory is recognized as goods are transferred to the customer.

The arrangement with Cipla contains consideration that is variable based on the customer’s achievement of certain development and regulatory milestones in addition to royalties upon the customer’s commercial success with the licensed product. As discussed previously, the next milestone payment the Company may be entitled to receive of $3.0 million related to the FDA’s acceptance of the first IND for the first CTP-354 product is considered variable consideration that is fully constrained due to the uncertainty associated to the achievement of the development milestone. The consideration related to royalties is also variable consideration that is fully constrained in accordance with the royalty recognition constraint. The variable consideration related to royalties will be recognized in the period the products are sold by Cipla and the Company has a present right to payment.

For the three months ended March 31, 2019, the Company recognized $1.0 million in revenue associated to the Transfer of License Performance Obligation.

9. Stock-Based Compensation

The Company’s equity incentive plans provide for the issuance of a variety of stock-based awards, including incentive stock options, nonstatutory stock options and awards of stock, to directors, officers and employees of the Company, as well as consultants and advisors to the Company. As of March 31, 2019, the Company has granted awards in the form of stock options and restricted stock units, or RSUs. The stock options generally have been granted with an exercise

price equal to the fair value of the underlying common stock on the date of grant, a vesting period of three or four years, and all options expire no later than ten years from the date of grant.

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Effective January 1, 2019, an additional 937,503 shares were added to the Company's 2014 Stock Incentive Plan, or the 2014 Plan, for future issuance pursuant to the terms of the 2014 Plan. As of March 31, 2019, there were 1,706,914 shares of common stock available for future award grants under the 2014 Plan.
Total stock-based compensation expense related to all stock-based options and awards recognized in the condensed consolidated statements of operations and comprehensive loss consisted of:

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 1,475	$ 1,527
General and administrative	1,454	1,772
Total stock-based compensation expense	$ 2,929	$ 3,299

Stock Options

Stock options are valued using the Black-Scholes-Merton option valuation model and compensation cost is recognized based on such fair value over the period of vesting. The weighted average fair value of options granted in the three months ended March 31, 2019 and 2018 reflect the following weighted-average assumptions:

	Three Months Ended March 31,			
	2019		2018	
Expected volatility	77.16	%	77.18	%
Expected term	6.0 years		6.0 years	
Risk-free interest rate	2.27	%	2.62	%
Expected dividend yield	—	%	—	%

For the three months ended March 31, 2019 and 2018, expected volatility was estimated using a weighted-average of the Company's historical volatility of its common stock and the historical volatility of the common stock of a group of similar companies that were publicly traded. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

The following table provides certain information related to the Company's outstanding stock options:

	Three Months Ended March 31,	
	2019	2018
	(in thousands, except per share data)	
Weighted average fair value of options granted, per option	$9.45	$18.70
Aggregate grant date fair value of options vested during the period	$2,442	$1,461
Total cash received from exercises of stock options	$805	$669
Total intrinsic value of stock options exercised	$879	$2,109

The following is a summary of stock option activity for the three months ended March 31, 2019:

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	Number of Option Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2018	3,557,406	$ 15.26		
Granted	828,650	$ 13.94		
Exercised	(154,321)	$ 9.63		
Forfeited or expired	(83,485)	$ 20.54		
Outstanding at March 31, 2019	4,148,250	$ 15.10	7.40	$ 4,558
Exercisable at March 31, 2019	2,163,739	$ 13.04	6.11	$ 4,085
Vested and expected to vest at March 31, 2019[1]	3,959,129	$ 14.99	7.31	$ 4,529

(1) This represents the number of vested stock option shares as of March 31, 2019, plus the number of unvested stock option shares that the Company estimated as of March 31, 2019 would vest, based on the unvested stock option shares at March 31, 2019 and an estimated forfeiture rate of 7%.

As of March 31, 2019, there was $21.2 million of unrecognized compensation cost related to stock options that are expected to vest. The stock option costs are expected to be recognized over a weighted average remaining vesting period of 2.8 years.

Restricted Stock Units

On July 6, 2017, the Company granted 0.5 million restricted stock units, or RSUs, to executives and employees. The awards granted to employees are service-based, whereas the awards granted to executives are a blend of service-based and performance-based. Assuming all service and performance conditions were achieved, fifty percent of the RSUs would vest on March 31, 2018, and the remaining fifty percent of the RSUs would vest on March 31, 2019. Certain executive awards were subject to the achievement of defined performance criteria prior to March 31, 2018, including the closing of the Asset Purchase Agreement with Vertex Pharmaceuticals, Inc. and the institution by the Patent Trial and Appeal Board ("PTAB") of the Post Grant Review ("PGR") petition filed by the Company against Incyte Corporation. In January 2018, the PTAB decided not to institute the PGR petition and, as a result, the corresponding performance-based awards did not vest on March 31, 2018.

The Company used the accelerated attribution method to recognize expense over the required service period based on its estimate of the number of performance-based awards that vested. For any change in the estimate of the number of performance-based awards that were probable of vesting, the Company cumulatively adjusted compensation expense in the period that the change in estimate was made.

RSUs are not included in issued and outstanding common stock until the shares are vested and released. As of March 31, 2019, all achieved RSUs had vested. The fair value of an RSU is measured based on the market price of the underlying common stock as of the date of grant.
The following is a summary of RSU activity, including both service-based and performance-based RSUs for the three months ended March 31, 2019:

	Number of RSU Shares	Weighted Average

		Grant Date Fair Value
Outstanding at December 31, 2018	228,150	$ 13.87
Granted	—	$ —
Released	(202,550)	$ 13.87
Forfeited	(25,600)	$ 13.87
Outstanding at March 31, 2019	—	$ —

As of March 31, 2019, there was no unrecognized compensation cost related to RSUs.

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10. Loss Per Share

Basic net loss per common share is calculated by dividing net loss allocable to common stockholders by the weighted-average common shares outstanding during the period, without consideration of common stock equivalents. For purposes of the diluted net loss per share calculation, common stock equivalents are excluded from the calculation if their effect would be anti-dilutive. As such, basic and diluted net loss per share applicable to common stockholders are the same for periods with a net loss.

The following table illustrates the determination of loss per share for each period presented.

	Three Months Ended March 31,	
	2019	2018
	(in thousands, expect per share amounts)	
Numerator:		
Net loss applicable to common stockholders - basic and diluted	$(21,826)	$(4,463)
Denominator:		
Weighted average shares outstanding - basic and diluted	23,508	23,223
Net loss per share applicable to common stockholders - basic and diluted	$(0.93)	$(0.19)
Anti-dilutive potential common stock equivalents excluded from the calculation of net loss per share:		
Stock options	448	973
Restricted stock units	187	367
Warrants	95	132

11. Lease

The FASB issued ASU 2016-02, or the leasing standard or ASC 842, in February 2016. ASU 2016-02 requires lessees to recognize assets and liabilities on the balance sheet for the rights and obligations created by all leases with terms of more than 12 months. ASU 2016-02 also requires certain qualitative and quantitative disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash flows arising from leases.

The Company has adopted ASU 2016-02, effective January 1, 2019. The Company has elected to employ the transitionary relief recently offered by the FASB under ASU 2018-11, and implement the new standard without the restatement of comparative periods' financial information. ASU 2018-11 also provides for recognizing the effects of applying ASU 2016-02 as a cumulative-effect adjustment to retained earnings as of January 1, 2019; however, no such adjustment was required as of January 1, 2019.

The Company has elected to employ the package of practical expedients offered under ASC 842, which allow the Company to not reassess the following:

- the presence of a lease in any expired or existing contracts;
- the lease classification for any expired or existing leases; and
- the initial direct costs for any existing leases.

The Company currently leases 55,522 square feet of office and laboratory space, or the Lease, located at 65 Hayden Avenue, Lexington, Massachusetts, or the Premises, which was classified as an operating lease under ASC 840. The Lease is also classified as an operating lease under ASC 842 in accordance with the Company's election of the practical expedient under ASC 842. Pursuant to the package of practical expedients, the Company will also not reassess initial direct costs for 65 Hayden Avenue. Additionally, the Company has made the policy election to adopt the practical expedient to not separate lease components from nonlease components for the right-to-use asset class of office and laboratory space. This policy election

results in the Company accounting for the lease component, the use of the Premises, and the non-lease components, which include the use of the parking garage, building elevators, and HVAC, as a single lease component.

The Company occupied the Premises in the third quarter of 2018; however the Company gained access to the space on January 1, 2018 in order to start making certain tenant improvements. Accordingly, for accounting purposes the lease commencement date was determined to be January 1, 2018 under the prior guidance of ASC 840, and therefore the Company had begun recognizing lease expense as of that date. The Lease term extends ten years following January 1, 2019. The Company is entitled to two five-year options to extend the Lease; however, these options were not included in the calculation of the Lease asset or liability. The Company has elected to employ the provision under ASC 842 to use hindsight with respect to determining the lease term (i.e., consideration of the actual outcome of lease renewals, termination options, and purchase options) and in assessing any impairment of right-of-use assets for existing leases. The Company notes no events such as renewals or termination options have occurred with the Lease of 65 Hayden Avenue. Therefore, the hindsight practical expedient under ASC 842 has no impact on the accounting term as previously determined under ASC 840. As of March 31, 2019, the remaining lease term for the Premises is 9 years and 9 months.

The Lease provides for annual base rent of approximately $2.8 million in the first year following the Base Rent Commencement Date of January 1, 2019, which increases on a yearly basis by 3.0% (subject to an abatement of base rent of approximately $0.5 million at the beginning of the second year of the Lease term if the Company is not in default under the Lease). There are no variable payments, exercise purchase options, penalties, fees, or residual value guarantees under the Lease. The Company is also obligated to pay the Landlord for certain costs, taxes and operating expenses related to the Premises, subject to certain exclusions; however the Company has concluded that these payments are not in-substance fixed payments and therefore are not included in the calculation of the related lease liability and asset under ASC 842.

The Company recorded the liability associated with the Lease of 65 Hayden Avenue at the present value of the lease payments not yet paid, discounted using the discount rate for the Lease established at the commencement date. As our Lease does not provide an implicit rate, the Company had to estimate the incremental borrowing rate, or IBR, as of the commencement date. The IBR is defined under ASC 842 as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments in a similar economic environment.

The IBR for the Lease was determined by establishing a credit rating of the Company using the Rank Order Model. Based on the established credit rating, the Company determined a borrowing rate using the Recovery Rate method, adjusted for the risk-free rate, which resulted in an IBR of approximately 13%. The Company used this IBR of 13% to discount the remaining lease payments over the remaining lease term and recorded a lease liability of $16.9 million on January 1, 2019. This lease liability will be amortized over the remaining lease term in an amount equal to the difference between the cash rent paid and the monthly interest calculated on the remaining lease liability. As of March 31, 2019, the Company had a current lease liability of $0.2 million and a non-current lease liability of $16.6 million recorded in its condensed consolidated balance sheets.

The Company received an improvement allowance from the Landlord of approximately $5.0 million for certain permitted costs related to the design of Company improvements to the Premises, consisting of normal tenant improvements. The Company is deemed to be the owner of these tenant improvements during the lease term. These $5.0 million of improvements are included in the Company’s property, plant and equipment balances in its condensed consolidated balance sheets as of March 31, 2019 and are depreciated over the shorter of their useful life or the related lease term.

On January 1, 2019, the Company recorded a right-of-use asset in the amount $9.5 million, which represents the lease liability of $16.9 million, adjusted for previously accrued rent of $2.9 million and previously recorded unamortized lease incentives (the improvement allowance) in the amount of $4.5 million. The right-of-use asset will be amortized over the remaining lease term in an amount equal to the difference between the calculated straight-line expense of the total lease payments less the monthly interest calculated on the remaining lease liability. As of March 31, 2019, the

Company had a long-term lease asset of $9.4 million recorded in its condensed consolidated balance sheets.

The Company will recognize lease expense, calculated as the remaining cost of the lease allocated over the remaining lease term on a straight-line basis. Lease expense will be presented as part of continuing operations in the condensed consolidated statement of operations and comprehensive loss. For the three months ended March 31, 2019, the Company recognized $0.6 million in lease expense.

For the three months ended March 31, 2019, the Company paid $0.7 million in rent relating to the Lease. As a payment arising from an operating lease, the $0.7 million will be classified within operating activities in the Condensed Consolidated Statements of Cash Flows.

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Supplemental cash flow information: (in thousands)	For the three months ended March 31, 2019
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows from operating leases	$ 694

Supplemental balance sheet information: (in thousands)	For the three months ended March 31, 2019	2018
Operating lease right-of-use assets	$9,430	$ —
Operating lease liability	16,727	—
Weighted average remaining lease term	9.75	10.29
Weighted average discount rate	13.08 %	—%

Maturities of lease liabilities: (in thousands)	For the twelve months ended December 31,	
2019	$ 2,084	*
2020	2,406	
2021	2,969	
2022	3,058	
2023	3,150	
Thereafter	17,223	
Total lease payments	30,890	
Less imputed interest	(14,163)	*
Total	$ 16,727	

* Excludes the three months ended March 31, 2019

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12. Open Market Sale Agreement

On March 1, 2019, the Company entered into an Open Market Sale Agreement, or the Agreement, with Jefferies LLC, or Jefferies, with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $50,000,000, referred to as Placement Shares, through Jefferies as its sales agent. The Company will pay Jefferies a commission equal to 3.0 percent (3.0%) of the gross sales proceeds of any Placement Shares sold through Jefferies under the Agreement, and also has provided Jefferies with customary indemnification and contribution rights. In addition, the Company has agreed to reimburse certain legal expenses and fees by Jefferies in connection with the offering up to a maximum of $50,000, in addition to certain ongoing disbursements of Jefferies' counsel. As of March 31, 2019 the Company incurred approximately $0.2 million related to legal, accounting and other fees in connection with the Agreement. The Company has not issued or sold any securities under the Agreement.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not based on historical fact are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, general and administrative expenses, research and development expenses, current and future development and manufacturing efforts, regulatory filings, nonclinical and clinical trial results, and the sufficiency of our cash for future operations. You should read the "Risk Factors" section in Part II—Item 1A. of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

OVERVIEW

We are a clinical stage biopharmaceutical company applying our extensive knowledge of deuterium chemistry to discover and develop novel small molecule drugs. Selective incorporation of deuterium into known molecules has the potential, on a case-by-case basis, to provide better pharmacokinetic or metabolic properties, thereby enhancing their clinical safety, tolerability or efficacy. Our approach typically starts with previously studied compounds, including approved drugs, which we believe may be improved with deuterium substitution. Our technology provides the opportunity to develop products that may compete with the non-deuterated drug in existing markets or to leverage its known activity to expand into new indications and may enable compounds not otherwise well-suited for human drug development to be clinically developed. Our deuterated chemical entity platform, or DCE Platform®, has broad potential across numerous therapeutic areas. The Company's pipeline includes multiple clinical-stage candidates and a number of preclinical compounds that it is currently assessing.

CTP-543

Background on Alopecia Areata

Alopecia areata is a chronic autoimmune disease affecting approximately 650,000 Americans at any given time that results in partial or complete loss of hair on the scalp and/or body. Alopecia areata occurs when the immune system attacks the hair follicles and is characterized as non-scarring hair loss. It presents in a number of patterns including:

- Patchy: coin-sized or larger patch or patches of hair loss;
- Totalis: no hair on the head; and
- Universalis: no hair anywhere on the body.

Onset can occur at any age including childhood, and it affects both women and men equally. While the average age of onset is between 25-35 years, the disease does occur in children, and onset in the first two decades is associated with more severe disease. The emotional effect of alopecia areata can be considerable and may result in anxiety and depression or affect personal attributes such as self-esteem and confidence. Alopecia areata may also be associated with other autoimmune conditions such as thyroid disease, vitiligo, allergic rhinitis, asthma, lupus, rheumatoid arthritis, and ulcerative colitis. The most common form

of treatment is corticosteroids including intralesional injections or topical application. However, they often are not an effective treatment option. There are currently no FDA-approved treatments for alopecia areata.

CTP-543 Opportunity

CTP-543 was discovered by applying Concert's deuterium chemistry technology to modify ruxolitinib, a Janus kinase ("JAK") inhibitor, which is commercially available under the name Jakafi® in the United States for the treatment of certain blood disorders.

In January 2018, we announced that the FDA had granted Fast Track designation to CTP-543 for the treatment of alopecia areata.

Clinical Development of CTP-543

In 2016, we completed single and multiple ascending dose Phase 1 trials with our investigational treatment CTP-543, which enrolled a total of 77 healthy volunteers. The pharmacokinetic measurements showed increased exposure with increasing doses of CTP-543. CTP-543 was well-tolerated across all dose groups and there were no serious adverse events reported in subjects who received CTP-543. In the multiple ascending dose Phase 1 trial of CTP-543, pharmacodynamic analyses were performed to assess the inhibition of IL-6- and IFN-gamma-mediated JAK/STAT signaling. Consistent with the expected pharmacological activity of a JAK1/JAK2 inhibitor, CTP-543 demonstrated a dose-related reduction of IL-6-stimulated phosphorylation of STAT3 in an ex-vivo assay. Also, IFN-gamma-mediated STAT1 signaling, which is believed to play a key role in the pathogenesis of alopecia areata, was significantly inhibited in disease-relevant immune cell types at all doses evaluated.

We also conducted a Phase 1 crossover study evaluating the metabolite profiles of CTP-543 and ruxolitinib. In this study, except for the presence of deuterium, no new metabolites were observed with CTP-543.

A Phase 2 double-blind, randomized, sequential dose-ranging trial to evaluate three sequential doses of CTP-543 (4, 8 and 12 mg twice daily) and a placebo control in patients with moderate-to-severe alopecia areata is ongoing. The primary outcome measure will utilize the severity of alopecia tool (SALT) after 24 weeks of dosing. In November 2018, we announced interim topline results from the 4 mg and 8 mg twice daily cohorts of our Phase 2 trial. At 24 weeks, patients treated with an 8 mg twice-daily dose of CTP-543 met the primary efficacy endpoint vs. placebo ($p < 0.001$), with patients achieving 50% relative reduction in SALT between Week 24 and baseline. Regrowth of hair did not appear to plateau at Week 24. In the primary analysis, the response observed in the 8 mg twice daily dose was significantly differ