Neos Therapeutics, Inc.
Form 10-Q
August 09, 2018
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended JUNE 30, 2018**

**OR**

o **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 001-37508**

# Neos Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

| **Delaware** | **2834** | **27-0395455** |
|---|---|---|
| State or Other Jurisdiction of Incorporation or Organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification Number) |

**2940 N. Hwy 360**

**Grand Prairie, TX 75050**

**(972) 408-1300**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

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

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

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 and smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

| | |
|---|---|
| Large accelerated filer o | Accelerated filer x |
| Non-accelerated filer o (Do not check if a Smaller reporting company) | Smaller reporting company o<br>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 o No x

The number of shares outstanding of the registrant s common stock as of August 3, 2018: 29,673,910 shares.

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**NEOS THERAPEUTICS, INC.**

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**Special note regarding forward-looking statements**

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as may, will, should, expects, plans, anticipates, could, intends, target, projects, contemplates, believes, estimates, predicts, potentia negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our anticipated cash needs and our estimates regarding our anticipated expenses, capital requirements and our needs for additional financings;

- our ability to commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or develop and commercialize any other future product or product candidate;

- the cost or other aspects of the future sales of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or the timing, cost or other aspects of the commercial launch and future sales of any other future product or product candidate;

- our ability to increase our manufacturing and distribution capabilities for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or any other future product or product candidate;

- the attention deficit hyperactivity disorder patient market size and market adoption of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER by physicians and patients;

- the therapeutic benefits, effectiveness and safety of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or any other future product or product candidate;

- our expectations regarding the commercial supply of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, or any other future products, or our generic Tussionex;

- our ability to receive, and the timing of any receipt of the U.S. Food and Drug Administration, ( FDA ), approvals, or other regulatory action in the United States and elsewhere, for any future product candidate;

- our expectations regarding federal, state and foreign regulatory requirements;

- our entry into the settlement and licensing agreement with Actavis Laboratories FL, Inc. ( Actavis ) the effect of our agreement with Actavis on its Abbreviated New Drug Application ( ANDA ) and with the FDA for a generic version of Adzenys XR-ODT, and the expected timing of the manufacture and marketing of Actavis s generic version of Adzenys XR-ODT under the ANDA;

- our product research and development activities, including the timing and progress of our clinical trials, and projected expenditures;

- issuance of patents to us by the U.S. Patent and Trademark Office and other governmental patent agencies;

- our ability to achieve profitability;

- our staffing needs; and

- the additional risks, uncertainties and other factors described under the caption Risk Factors in this Quarterly Report on Form 10-Q.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and

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other factors described in Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

Furthermore, this Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

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**PART I FINANCIAL INFORMATION**

**ITEM 1. CONDENSED FINANCIAL STATEMENTS.**

**Neos Therapeutics, Inc. and Subsidiaries**

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

| | June 30, 2018 | December 31, 2017 (as adjusted) |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 18,318 | $ 31,969 |
| Short-term investments | 9,722 | 18,448 |
| Accounts receivable, net of allowances for chargebacks and cash discounts of $788 and $1,154, respectively | 17,977 | 13,671 |
| Inventories | 12,713 | 11,732 |
| Other current assets | 1,336 | 3,575 |
| **Total current assets** | 60,066 | 79,395 |
| | | |
| Property and equipment, net | 8,269 | 8,203 |
| Intangible assets, net | 15,507 | 16,348 |
| Other assets | 150 | 162 |
| | | |
| **Total assets** | $ 83,992 | $ 104,108 |
| | | |
| **LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)** | | |
| | | |
| Current Liabilities: | | |
| Accounts payable | $ 6,060 | $ 11,460 |
| Accrued expenses | 34,128 | 20,944 |
| Current portion of long-term debt | 15,983 | 896 |
| | | |
| **Total current liabilities** | 56,171 | 33,300 |
| | | |
| Long-Term Liabilities: | | |
| Long-term debt, net of current portion | 43,932 | 58,938 |
| Derivative liability | 1,311 | 1,660 |
| Deferred rent | 1,036 | 1,083 |
| Other long-term liabilities | 178 | 180 |
| | | |
| **Total long-term liabilities** | 46,457 | 61,861 |
| | | |
| Stockholders Equity (Deficit): | | |
| Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at June 30, 2018 and December 31, 2017 | | |
| Common stock, $0.001 par value, 100,000,000 authorized at June 30, 2018 and December 31, 2017; 29,048,589 and 29,014,788 issued and outstanding at June 30, 2018, respectively; | 29 | 29 |

| | | | | |
|---|---|---|---|---|
| 29,030,757 and 28,996,956 issued and outstanding at December 31, 2017, respectively | | | | |
| Treasury stock, at cost, 33,801 shares at June 30, 2018 and December 31, 2017 | | (352) | | (352) |
| Additional paid-in capital | | 276,637 | | 274,584 |
| Accumulated deficit | | (294,951) | | (265,308) |
| Accumulated other comprehensive income (loss) | | 1 | | (6) |
| **Total stockholders equity (deficit)** | | (18,636) | | 8,947 |
| **Total liabilities and stockholders equity** | $ | 83,992 | $ | 104,108 |

See notes to condensed consolidated financial statements.

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**Neos Therapeutics, Inc. and Subsidiaries**

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 (as adjusted) | 2018 | 2017 (as adjusted) |
| Revenues: | | | | |
| Net product sales | $ 11,363 | $ 5,179 | $ 22,092 | $ 10,810 |
| Cost of goods sold | 6,987 | 2,817 | 12,208 | 7,567 |
| **Gross profit** | 4,376 | 2,362 | 9,884 | 3,243 |
| Research and development | 2,381 | 3,692 | 4,072 | 5,416 |
| Selling and marketing expenses | 11,557 | 11,706 | 24,547 | 22,412 |
| General and administrative expenses | 3,705 | 3,316 | 7,051 | 6,854 |
| **Loss from operations** | (13,267) | (16,352) | (25,786) | (31,439) |
| Interest expense | (2,232) | (2,390) | (4,452) | (4,602) |
| Other income, net | 292 | 97 | 595 | 175 |
| **Net loss** | $ (15,207) | $ (18,645) | $ (29,643) | $ (35,866) |
| Weighted average common shares outstanding used to compute net loss per share, basic and diluted | 29,008,909 | 22,613,382 | 29,002,966 | 21,127,303 |
| **Net loss per share of common stock, basic and diluted** | $ (0.52) | $ (0.82) | $ (1.02) | $ (1.70) |

See notes to condensed consolidated financial statements.

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**Neos Therapeutics, Inc. and Subsidiaries**

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 (as adjusted) | 2018 | 2017 (as adjusted) |
| **Net loss** | $ (15,207) | $ (18,645) | $ (29,643) | $ (35,866) |
| Other comprehensive income (loss): | | | | |
| Net unrealized gain (loss) on short-term investments | 4 | (3) | 7 | (5) |
| **Total other comprehensive income (loss)** | $ 4 | $ (3) | $ 7 | $ (5) |
| **Comprehensive loss** | $ (15,203) | $ (18,648) | $ (29,636) | $ (35,871) |

See notes to condensed consolidated financial statements.

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**Neos Therapeutics, Inc. and Subsidiaries**

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

Six months ended June 30, 2018

(In thousands, except shares)

(unaudited)

| | Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-in | Accumulated | Accumulated Other Comprehensive | Total Stockholders |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Capital | Deficit | Income (Loss) | Equity (Deficit) |
| Balance, December 31, 2017 (as adjusted) | | $ | 29,030,757 | $ 29 | (33,801) | $ (352) | $ 274,584 | $ (265,308) | $ (6) | $ 8,947 |
| Issuance of common stock upon RSU conversion | | | 17,832 | | | | | | | |
| Share-based compensation expense | | | | | | | 2,053 | | | 2,053 |
| Net unrealized gain on investments | | | | | | | | | 7 | 7 |
| Net loss | | | | | | | | (29,643) | | (29,643) |
| Balance, June 30, 2018 | | $ | 29,048,589 | $ 29 | (33,801) | $ (352) | $ 276,637 | $ (294,951) | $ 1 | $ (18,636) |

See notes to condensed consolidated financial statements.

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**Neos Therapeutics, Inc. and Subsidiaries**

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

| | Six months ended June 30, | |
|---|---|---|
| | **2018** | **2017 (as adjusted)** |
| Cash Flows From Operating Activities: | | |
| Net loss | $ (29,643) | $ (35,866) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation expense | 2,053 | 1,933 |
| Depreciation and amortization of property and equipment | 850 | 643 |
| Amortization of patents and other intangible assets | 869 | 817 |
| Changes in fair value of earnout, derivative and warrant liabilities | (349) | |
| Deferred interest on debt | | 2,111 |
| Amortization of senior debt discounts | 427 | 245 |
| Amortization of short-term investment purchase discounts | (106) | |
| Loss (gain) on sale of equipment | 1 | (33) |
| Other adjustments | (47) | (95) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (4,306) | 466 |
| Inventories | (981) | 20 |
| Deferred contract sales organization fees | | 720 |
| Other assets | 2,251 | 730 |
| Accounts payable | (5,400) | 180 |
| Accrued expenses | 13,184 | 5,874 |
| **Net cash used in operating activities** | (21,197) | (22,255) |
| Cash Flows From Investing Activities: | | |
| Purchases of short-term investments | (17,904) | (26,821) |
| Sales and maturities of short-term investments | 26,743 | 21,021 |
| Proceeds from sale-leaseback of equipment | | 3,222 |
| Capital expenditures | (814) | (1,776) |
| Intangible asset expenditures | (28) | (49) |
| **Net cash provided by (used in) investing activities** | 7,997 | (4,403) |
| Cash Flows From Financing Activities: | | |
| Proceeds from the issuance of common stock, net of issuance costs | | 60,087 |
| Payments made on borrowings | (451) | (379) |
| Payments made on behalf of Deerfield | | (40) |
| **Net cash (used in) provided by financing activities** | (451) | 59,668 |
| **(Decrease) increase in cash and cash equivalents** | (13,651) | 33,010 |
| Cash and Cash Equivalents: | | |

| | | | | |
|---|---|---|---|---|
| Beginning | | 31,969 | | 24,352 |
| Ending | $ | 18,318 | $ | 57,362 |
| | | | | |
| Supplemental Disclosure of Noncash Transactions: | | | | |
| Acquired equipment under capital lease | $ | 105 | $ | |
| Capital lease liability from purchase of equipment | $ | 105 | $ | |
| Issuance of senior secured convertible notes | $ | | $ | 6,586 |
| Capital lease liability from sale-leaseback transactions | $ | | $ | 3,222 |
| Derivative liability incurred in connection with First Amendment to Facility | $ | | $ | 2,043 |
| Beneficial conversion feature incurred on convertible notes | $ | | $ | 613 |
| Deferred contract sales organization fees | $ | | $ | 312 |
| Supplemental Cash Flow Information: | | | | |
| Interest paid | $ | 4,116 | $ | 2,249 |

See notes to condensed consolidated financial statements.

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**Neos Therapeutics, Inc. and Subsidiaries**

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**Note 1. Organization and nature of operations**

Neos Therapeutics, Inc., a Delaware corporation, and its subsidiaries (the Company ) is a fully integrated pharmaceutical company. The Company has developed a broad, proprietary modified-release drug delivery technology that enables the manufacture of single and multiple ingredient extended-release pharmaceuticals in patient- and caregiver-friendly orally disintegrating tablet and liquid suspension dosage forms. The Company has a pipeline of extended-release pharmaceuticals including three approved products for the treatment of attention deficit hyperactivity disorder ( ADHD ). Adzenys XR-ODT was approved by the US Food and Drug Administration (the FDA ) on January 27, 2016 and launched commercially on May 16, 2016. The Company received approval from the FDA for Cotempla XR-ODT, its methylphenidate XR-ODT for the treatment of ADHD in patients 6 to 17 years old, on June 19, 2017, the Company initiated an early experience program with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017. Also, the Company received approval from the FDA for Adzenys ER oral suspension ( Adzenys ER ) on September 15, 2017 and launched this product on February 26, 2018. In addition, the Company manufactures and markets a generic Tussionex (hydrocodone and chlorpheniramine) ( generic Tussionex ), extended-release liquid suspension for the treatment of cough and upper respiratory symptoms of a cold.

**Note 2. Summary of significant accounting policies**

*Basis of presentation:* The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ( U.S. GAAP ), for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC ), for reporting on Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and footnotes necessary for a complete presentation of financial position, results of operations, and cash flows. In the opinion of management, all adjustments (consisting of normal, recurring adjustments) necessary for a fair presentation of results of operations for and financial condition as of the end of the interim period have been included. Results of operations for the three and six months ended June 30, 2018 are not necessarily indicative of the results for the year ending December 31, 2018 or any period thereafter. The audited consolidated financial statements as of and for the year ended December 31, 2017 included information and footnotes necessary for such presentation and were included in the Neos Therapeutics, Inc. Annual Report on Form 10-K and filed with the SEC on March 16, 2018. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2017.

*Principles of consolidation:* At June 30, 2018 and December 31, 2017 and for the three and six months ended June 30, 2018 and 2017, the condensed consolidated financial statements include the accounts of the Company and its four wholly-owned subsidiaries. All significant intercompany transactions have been eliminated.

*Use of estimates:* The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates.

*Reclassifications:* In 2017, the Company reclassified certain patents from Other assets to Intangible assets, net as reported on the condensed consolidated balance sheets.

*Liquidity:* During 2017 and the six months ended June 30, 2018, the Company produced operating losses and used cash to fund operations. Management intends to achieve profitability through revenue growth from pharmaceutical products developed with its extended-release technologies. The Company does not anticipate it will be profitable until after the successful commercialization of its approved products, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Accordingly, management has performed the review required for going concern accounting and believes the Company presently has sufficient liquidity to continue to operate for the next twelve months after the filing of this Report on Form 10-Q. The Company continues to evaluate alternatives to restructure or replace its debt and has considerable discretion over its operating expenses as options to supplement revenue to meet its cash needs. If the Company does not restructure or replace its debt or raise sufficient funds from other sources, the Company may not be able to meet its obligations over the next twelve months.

*Cash equivalents:* The Company invests its available cash balances in bank deposits and money market funds. The Company considers highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position

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of the depository institutions in which those deposits are held. The Company s primary objectives for investment of available cash are the preservation of capital and the maintenance of liquidity.

*Short-term investments:* Short-term investments consist of debt securities that have original maturities greater than three months but less than or equal to one year and are classified as available-for-sale securities. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported, net of material tax effects reported, as accumulated other comprehensive income or loss, which is a separate component of stockholders equity. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in other income (expense) in the consolidated results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income are recognized in other income when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments with government agencies, or corporate institutions whose debt is rated as investment grade. The Company classifies all available-for-sale marketable securities with maturities greater than one year from the balance sheet date, if any, as non-current assets.

*Inventories:* Inventories are measured at the lower of cost (first in, first out) or net realizable value. Inventories have been reduced by an allowance for excess and obsolete inventories. Cost elements include material, labor and manufacturing overhead. Inventories consist of raw materials, work in process and finished goods.

Until objective and persuasive evidence exists that regulatory approval has been received and future economic benefit is probable, pre-launch inventories are expensed into research and development. Manufacturing costs for the production of Adzenys XR-ODT incurred after the January 27, 2016 FDA approval date, for the production of Cotempla XR-ODT incurred after June 30, 2017, following the FDA approval date of June 19, 2017, and for the production of Adzenys ER incurred after September 30, 2017, following the FDA approval date of September 15, 2017, are being capitalized into inventory.

*Derivative liabilities:* The Company evaluates its debt and equity issuances to determine if those contracts or embedded components of those contracts qualify as derivatives requiring separate recognition in the Company s financial statements. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market each balance sheet date and recorded as a liability and the change in fair value is recorded in other income (expense) in the consolidated results of operations. In circumstances where the embedded conversion option in a convertible instrument is required to be bifurcated and there are also other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within twelve months of the balance sheet date.

When the Company has determined that the embedded conversion options should not be bifurcated from their host instruments, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption and are classified in interest expense in the consolidated results of operations.

*Intangible assets*: Intangible assets subject to amortization, which principally include proprietary modified-release drug delivery technology, the costs to acquire the rights to Tussionex Abbreviated New Drug Application ( Tussionex ANDA ) and patents, are recorded at cost and amortized over the estimated lives of the assets, which primarily range from 10 to 20 years. The Company estimates that the patents it has filed have a future beneficial value. Therefore, costs associated with filing for its patents are capitalized. Once the patent is approved and commercial revenue realized, the costs associated with the patent are amortized over the useful life of the patent. If the patent is not approved, the costs will be expensed.

*Revenue recognition:* Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company makes estimates of the net sales price, including estimates of variable consideration (e.g., savings offers, prompt payment discounts, product returns, wholesaler fees, wholesaler chargebacks and estimated rebates) to be incurred on the selling price of the respective product sales, and recognizes the estimated amount as revenue when it transfers control of the product to its customers (e.g., upon delivery). Variable consideration is determined using either an expected

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value or a most likely amount method. The estimate of variable consideration is also subject to a constraint such that some or all of the estimated amount of variable consideration will only be included in the transaction price to the extent that it is probable that a significant reversal of revenue (in the context of the contract) will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint will require the use of significant management judgment and other market data. The Company provides for prompt payment discounts, wholesaler fees and wholesaler chargebacks based on customer contractual stipulations. The Company analyzes recent product return history and other market data obtained from its third party logistics providers ( 3PLs ) to determine a reliable return rate. Additionally, management analyzes historical savings offers and rebate payments based on patient prescriptions dispensed for Adzenys XR ODT, Cotempla XR ODT and Adzenys ER and information obtained from third party providers to determine these respective variable considerations.

The Company sells its generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to a limited number of pharmaceutical wholesalers, all subject to rights of return. Pharmaceutical wholesalers buy drug products directly from manufacturers. Title to the product passes upon delivery to the wholesalers, when the risks and rewards of ownership are assumed by the wholesaler (freight on board destination). These wholesalers then resell the product to retail customers such as food, drug and mass merchandisers.

The Company views its operations and manages its business in one operating segment, which is the development, manufacturing and commercialization of pharmaceuticals.

*Disaggregation of revenue*

The following table disaggregates the Company s net product sales by product:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 (as adjusted) | 2018 | 2017 (as adjusted) |
| Adzenys XR-ODT | $ 6,516 | $ 4,439 | $ 11,508 | $ 7,552 |
| Cotempla XR-ODT | 4,342 | | 7,989 | |
| Adzenys ER | (28) | | 175 | |
| Generic Tussionex | 533 | 740 | 2,420 | 3,258 |
| | $ 11,363 | $ 5,179 | $ 22,092 | $ 10,810 |

*Net product sales*

Net product sales represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER include savings offers, prompt payment discounts, wholesaler fees, estimated rebates to be incurred on the selling price of the respective product sales and estimated allowances for product returns.

Gross to net sales adjustments for generic Tussionex include prompt payment discounts, estimated allowances for product returns, wholesaler fees, estimated government rebates and estimated chargebacks to be incurred on the selling price of generic Tussionex related to the respective product sales.

The Company recognizes total gross product sales less gross to net sales adjustments as revenue based on shipments from 3PLs to the Company s wholesaler customers.

*Savings offers for branded products*

The Company offers savings programs for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. The Company records the amount of redeemed savings offers based on information from third-party providers against the estimated discount recorded as accrued expenses. The estimated discount is recorded as a gross to net sales adjustments at the time revenue is recognized.

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*Prompt payment discounts*

Prompt payment discounts are based on standard programs with wholesalers and are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized.

*Wholesale distribution fees*

Wholesale distribution fees are based on definitive contractual agreements for the management of the Company s products by wholesalers and are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized.

*Rebates*

The Company s branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER are subject to commercial managed care and government managed Medicare and Medicaid programs whereby discounts and rebates are provided to participating managed care organizations and federal and/or state governments. Calculations related to rebate accruals of branded products are estimated based on information from third-party providers.

The Company s generic Tussionex product is subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. Generic Tussionex government rebates are estimated based upon rebate payment data available from sales of the Company s generic Tussionex product over the past three years.

Estimated rebates are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized. Historical trends of estimated rebates will be continually monitored and may result in future adjustments to such estimates.

*Product returns*

Wholesalers contractual return rights are limited to defective product, product that was shipped in error, product ordered by customer in error, product returned due to overstock, product returned due to dating or product returned due to recall or other changes in regulatory guidelines. The return policy for expired product allows the wholesaler to return such product starting six months prior to expiry date to twelve months post expiry date. Estimated returns are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized.

The Company analyzed recent branded product return history and other market data obtained from the Company s 3PLs to determine a reliable return rate for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Generic Tussionex product returns were estimated based upon return data available from sales of the Company s generic Tussionex product over the past three years.

*Wholesaler chargebacks for generic product*

The Company s generic Tussionex products are subject to certain programs with wholesalers whereby pricing on products is discounted below wholesaler list price to participating entities. These entities purchase products through wholesalers at the discounted price, and the wholesalers charge the difference between their acquisition cost and the discounted price back to the Company. Estimated chargebacks are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized based on information provided by third parties.

Due to estimates and assumptions inherent in determining the amount of generic Tussionex returns, rebates and chargebacks, the actual amount of returns, claims for rebates and chargebacks may be different from the estimates, at which time reserves would be adjusted accordingly. Wholesale distribution fees and the allowance for prompt pay discounts are recorded at the time of shipment and such fees and allowances are recorded in the same period that the related revenue is recognized.

*Research and development costs:* Research and development costs are charged to operations when incurred and include salaries and benefits, facilities costs, overhead costs, raw materials, laboratory and clinical supplies, clinical trial costs, contract services, fees paid to regulatory authorities for review and approval of the Company s product candidates and other related costs.

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*Advertising costs:* Advertising costs are comprised of print and electronic media placements that are expensed as incurred. The Company recognized advertising costs of $219,000 and $450,000 during the three and six months ended June 30, 2018, respectively, and advertising costs of $10,000 and $248,000 during the three and six months ended June 30, 2017, respectively.

*Share-based compensation:* Share-based compensation awards, including grants of employee stock options, restricted stock, restricted stock units ( RSUs ) and modifications to existing stock options, are recognized in the statement of operations based on their fair values. Compensation expense related to awards to employees is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. The fair value of the Company s stock-based awards to employees and directors is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends.

Due to the previous lack of a public market for the trading of its common stock and a lack of company-specific historical and implied volatility data, the Company had, prior to the Initial Public Offer of the Company s common shares ( IPO ), historically utilized third party valuation analyses to determine the fair value. After the closing of the Company s IPO, the Company s board of directors has determined the fair value of each share of underlying common stock based on the closing price of the Company s common stock as reported by the NASDAQ Global Market on the date of grant.

Under new guidance for accounting for share-based payments, the Company has elected to continue estimating forfeitures at the time of grant and, if necessary, revise the estimate in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the actual expense recognized over the vesting period will only be for those options that vest.

*Paragraph IV litigation costs:* Legal costs incurred by the Company in the enforcement of the Company s intellectual property rights are charged to expense as incurred.

*Income taxes:* Income taxes are accounted for using the liability method, under which deferred taxes are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax laws that will be in effect when the differences are expected to reverse.

Management evaluates the Company s tax positions in accordance with guidance on accounting for uncertainty in income taxes. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not that the position will be sustained upon examination. As of June 30, 2018 and December 31, 2017, the Company has unrecognized tax benefits associated with uncertain tax positions in the consolidated financial statements. These uncertain tax positions were netted against net operating losses (NOL s) with no separate reserve for uncertain tax positions required.

Deferred tax assets should be reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized. In evaluating the objective evidence that historical results provide, the Company considered that three years of cumulative operating losses was significant negative evidence outweighing projections for future taxable income. Therefore, at June 30, 2018 and December 31, 2017, the Company determined that it is more likely than not that the deferred tax assets will not be realized. Accordingly, the Company has recorded a valuation allowance to reduce deferred tax assets to zero. The Company may not ever be able to realize the benefit of some or all of the federal and state loss carryforwards, either due to ongoing operating losses or due to ownership changes, which limit the usefulness of the loss carryforwards.

*Recent accounting pronouncements:* In March 2018, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2018-05, *Income Taxes (Topic 740) Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*, which was issued to state the income tax accounting implications of the Tax Cuts and Jobs Act of 2017 (the TCJA ). The guidance clarifies the measurement period timeframe, changes in subsequent reporting periods and reporting requirements as a result of the TCJA. The measurement period begins in the period that includes the TCJA s enactment date, which was December 22, 2017, and as a result the Company has reflected the impact of this ASU on the deferred tax calculation as of December 31, 2017.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the TCJA, and requires certain disclosures about stranded tax effects. ASU 2018-02 is effective for entities for fiscal years beginning after December 15, 2018 with early adoption permitted, and shall be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the corporate income tax rate in the TCJA is

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recognized. The Company will adopt this standard on January 1, 2019. The adoption of this standard will not have a material impact on the Company s consolidated results of operations or financial position.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation Stock Compensation (Topic 718): Scope of Modification Accounting.* This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the modification. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. This standard became effective for the Company on January 1, 2018. The adoption of this standard did not have a material impact on the Company s consolidated results of operations or financial position.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This ASU was designed to reduce the diversity in practice of how the eight specified items are presented and classified in the statement of cash flows, including debt prepayment or debt extinguishment costs. The amendments are effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those years. This standard became effective for the Company on January 1, 2018. The adoption of this standard did not have a significant effect on the Company s ongoing financial reporting as the Company had classified its debt prepayment and debt extinguishment costs in the Condensed Consolidated Statements of Cash Flows in accordance with the amendments.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee s obligation to make lease payments arising from a lease, measured on a discounted basis; and 2) a right-of-use asset, which is an asset that represents the lessee s right to use, or control the use of, a specified asset for the lease term. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. In January 2018, the FASB issued ASU No. 2018-01, *Land Easement Practical Expedient for Transition to Topic 842, Leases (Topic 842)*, which adds two practical expedients to the new lease guidance. The amendment and this ASU are effective for fiscal years beginning after December 15, 2018, including interim periods within those years. The new standard must be adopted using a modified retrospective transition and requires application of the new guidance at the beginning of the earliest comparative period presented. The Company is evaluating the effect that the standard will have on its consolidated financial statements and related disclosures and has not determined the expected impact at this time.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (the New Revenue Standard ). The New Revenue Standard replaces transaction and industry-specific revenue recognition guidance under current U.S. GAAP with a principles-based approach for determining revenue recognition. The New Revenue Standard requires an entity to recognize the amount of revenue based on the value of transferred goods or services to customers. There is also additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

The New Revenue Standard became effective for the Company on January 1, 2018. For purposes of providing comparable periods upon adoption, the Company applied the full retrospective transition method, which required the Company to restate each prior reporting period presented. The impact of the New Revenue Standard relates to the Company s accounting for branded net product sales. There are no changes to the net product sales of generic Tussionex revenue since the Company has estimated product returns since inception of recognizing revenue in August 2014.

The Company implemented internal controls and key system functionality to enable the preparation of financial information and reached conclusions on key accounting assessments related to the New Revenue Standard, including management s assessment that the impact of accounting for costs incurred to obtain a contract is immaterial.

Refer to Impacts to Previously Reported Results below for the impact of adoption of the New Revenue Standard included in the Company s condensed consolidated statements of operations.

**Impacts to Previously Reported Results**

Adoption of the new revenue standard impacted the Company s previously reported results as follows:

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| Condensed consolidated statement of operations | As Previously Reported | Three Months Ended June 30, 2017 New Revenue Standard Adjustment | As Adjusted |
|---|---|---|---|
| | (in thousands, except per share amounts) | | |
| Revenue: net product sales | $ 4,909 | $ 270 | $ 5,179 |
| Cost of goods sold | 2,576 | 241 | 2,817 |
| Gross profit | 2,333 | 29 | 2,362 |
| Net loss attributable to common stock | (18,674) | 29 | (18,645) |
| Net loss per share of common stock, basic and diluted | (0.83) | | (0.82) |

| Condensed consolidated statement of operations | As Previously Reported | Six Months Ended June 30, 2017 New Revenue Standard Adjustment | As Adjusted |
|---|---|---|---|
| | (in thousands, except per share amounts) | | |
| Revenue: net product sales | $ 10,536 | $ 274 | $ 10,810 |
| Cost of goods sold | 7,191 | 376 | 7,567 |
| Gross profit | 3,345 | (102) | 3,243 |
| Net loss attributable to common stock | (35,764) | (102) | (35,866) |
| Net loss per share of common stock, basic and diluted | (1.69) | | (1.70) |

| Condensed consolidated balance sheet | As Previously Reported | December 31, 2017 New Revenue Standard Adjustment | As Adjusted |
|---|---|---|---|
| | (in thousands) | | |
| Inventories | $ 13,459 | $ (1,727) | $ 11,732 |
| Other current assets | 5,093 | (1,518) | 3,575 |
| Total current assets | 82,640 | (3,245) | 79,395 |
| Accrued expenses | 10,570 | 10,374 | 20,944 |
| Deferred revenue | 14,676 | (14,676) | |
| Total current liabilities | 37,602 | (4,302) | 33,300 |
| Accumulated deficit | (266,365) | (1,057) | (265,308) |
| Total liabilities and stockholder equity | 107,353 | (3,245) | 104,108 |

Adoption of the New Revenue Standard had no impact to cash from or used in operating, financing, or investing activities on the Company s consolidated statements of cash flows.

From time to time, additional new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

**Note 3. Net l**