# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

## CURRENT REPORT

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

**Date of Report (Date of earliest event reported): May 9, 2017**

# OREXIGEN THERAPEUTICS, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-33415** | **65-1178822** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **3344 N. Torrey Pines Court, Suite 200 La Jolla, California** | **92037** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (858) 875-8600**

**Not Applicable**
**(Former Name or Former Address, if Changed Since Last Report)**

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company ☐

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

**Item 2.02 Results of Operations and Financial Condition**

On May 9, 2017, Orexigen Therapeutics, Inc. ("***Orexigen***" or the "***Company***") issued a press release announcing its financial results for the three months ended March 31, 2017. A copy of this press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the " ***Exchange Act***"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits**

(d) *Exhibits.*

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated May 9, 2017 |

**SIGNATURES**

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

**OREXIGEN THERAPEUTICS, INC.**

Date: May 9, 2017

By: /s. Michael A. Narachi
Name: Michael A. Narachi
Title: Chief Executive Officer

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release, dated May 9, 2017 |

EXHIBIT 99.1

**Orexigen Therapeutics Reports Financial Results for the First Quarter Ended March 31, 2017**

SAN DIEGO, May 9, 2017 /PRNewswire/ -- Orexigen Therapeutics, Inc. (Nasdaq: OREX) today announced business and financial results for the first quarter ended March 31, 2017.

"During the first quarter of 2017, the team at Orexigen delivered dramatic growth of U.S. Contrave sales and a clear trend break from prior performance," said Mike Narachi, CEO of Orexigen. He continued, "Our commercial model continues to evolve, and we expect it to become increasingly effective *and* more efficient, which we believe positions Orexigen to deliver strong, sustainable growth as we advance towards profitability. It's been an exciting start to 2017, and we look forward to providing additional updates regarding our performance throughout the year."

Adding to Mike's comments, Dr. Thomas Cannell, Chief Operating Officer and President of Global Commercial Products said, "Since the start of the year, our patient-centric campaign has been in full swing and our sales force has consistently been exceeding expectations. During the first quarter of 2017, Contrave established new all-time highs for nearly a dozen prescription volume and share metrics since the product was launched. Our telemedicine pilot program has also demonstrated early signs of success in California and Texas, and we're now targeting the expansion of the offering to 47 total states by the end of May. The combined effect of this novel, broadly-integrated commercial effort is clearly visible in our prescription-volume and net-sales performance to date."

**First Quarter 2017 business highlights:**

- Delivered strong prescription growth for Contrave® (naltrexone HCl and bupropion HCl extended-release tablets) in the United States, achieving new all-time highs across a broad range of key metrics including weekly total prescription volume and market share
- Achieved 39% growth in prescriptions in the United States in Q1 2017 versus Q4 2016
- Achieved 22% growth in average net revenue per unit sold in the United States compared to the first quarter of 2016
- Continued with the rollout of a comprehensive digital and social-media marketing strategy, including the launches of Contrave Facebook and Instagram pages
- Initiated the expansion of the Contrave telemedicine pilot from two states, Texas and California, to a target of 47 states by the end of May 2017
- Executed a distribution agreement with Bruno Farmaceutici S.p.A. for the commercialization of Mysimba in Italy
- Negotiated the recently-executed distribution arrangement with Navamedic ASA for the commercialization of Mysimba in Denmark, Finland, Norway, Sweden and Iceland
- Worked with our partner Laboratorios Farmacéuticos Rovi to launch Mysimba in Spain, and our partner Valeant to launch in six additional countries in Central and Eastern Europe

- Reduced debt by approximately $7.2 million following the completion of an exchange of our convertible notes

**Business and financial results for the three months ended March 31, 2017**

According to IMS Health, 195,920 total prescriptions of Contrave were filled in the first quarter of 2017, as compared to 192,005 total prescriptions filled in the first quarter of 2016.

Orexigen reported first quarter 2017 revenue of $19.1 million, including $14.8 million in net sales of Contrave in the United Sates and $4.3 million in net sales to partners outside the United States. In the first quarter of 2016, Orexigen reported total revenues of $5.0 million, which included royalties earned on approximately $13.2 million of US net sales as reported by our former partner. The increase in net sales was primarily attributable to growth in net revenue per unit sold in the United States and product shipments to support launches by our partners outside the United States.

Total operating expenses for the first quarter of 2017 were $66.8 million compared to $28.4 million for the first quarter of 2016. This overall increase in operating expense was due primarily to costs related to establishing and managing sales, marketing and distribution capabilities associated with commercializing Contrave in the United States, including the launch of patient-activation strategies. Operating expenses in the first quarter of 2017 also included $3.4 million of non-cash expense from the amortization of intangible assets and a change in the fair market value of contingent consideration related to the acquisition of Contrave in 2016.

For the three months ended March 31, 2017, Orexigen reported a net loss of $69.1 million, or $4.67 per share, as compared to a net loss of $22.3 million, or $1.54 per share, for the first quarter of 2016.

As of March 31, 2017, Orexigen had $126.6 million in cash, restricted cash and cash equivalents and marketable securities.

**Conference Call Today at 2:00 p.m. Pacific Time (5:00 p.m. Eastern Time)**

The Orexigen management team will host a teleconference and webcast to discuss the first quarter 2017 financial results and recent business highlights. The live call may be accessed by phone by calling (800) 708-4540 (domestic) or (847) 619-6397 (international), participant code 44748374. The webcast can be accessed live on the “Investors” section of the Orexigen web site at http://www.orexigen.com, and will be archived for 14 days following the call.

**About Contrave and Mysimba**

Contrave, approved by the United States Food and Drug Administration in September 2014, is indicated for use as an adjunct to a reduced-calorie diet and increased physical activity for chronic

weight management in adults with an initial body mass index (BMI) of 30 kg/m$^2$ or greater (obese), or 27 kg/m$^2$ or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia). In the European Union, the medicine was approved in March 2015 with the brand name Mysimba.

Further information can be found at http://www.contrave.com.

**Important Safety Information for CONTRAVE and MYSIMBA**

**(naltrexone HCl and bupropion HCl) 8 mg/90 mg extended-release tablets**

**One of the ingredients in CONTRAVE, bupropion, may increase the risk of suicidal thinking in children, adolescents, and young adults. CONTRAVE patients should be monitored for suicidal thoughts and behaviors. In patients taking bupropion for smoking cessation, serious neuropsychiatric events have been reported. CONTRAVE is not approved for use in children under the age of 18.**

**Stop taking CONTRAVE and call a healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:** thoughts about suicide or dying; attempts to commit suicide; depression; anxiety; feeling agitated or restless; panic attacks; trouble sleeping (insomnia); irritability; aggression, anger, or violence; acting on dangerous impulses; an extreme increase in activity and talking (mania); other unusual changes in behavior or mood.

**Do not take CONTRAVE if you**have uncontrolled high blood pressure; have or have had seizures; use other medicines that contain bupropion such as WELLBUTRIN, APLENZIN or ZYBAN; have or have had an eating disorder; are dependent on opioid pain medicines or use medicines to help stop taking opioids such as methadone or buprenorphine, or are in opiate withdrawal; drink a lot of alcohol and abruptly stop drinking; are allergic to any of the ingredients in CONTRAVE; or are pregnant or planning to become pregnant.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**Do not take any other medicines while you are taking CONTRAVE unless your healthcare provider says it is okay.**

**Tell your healthcare provider about all of your medical conditions, especially:** depression or other mental illnesses; attempted suicide; seizures; head injury; tumor or infection of brain or spine; low blood sugar or low sodium; liver or kidney problems; high blood pressure; heart attack, heart problems, or stroke; eating disorder; drinking a lot of alcohol; prescription medicine or street drug abuse; are 65 or older; diabetes; pregnant; or breastfeeding.

**CONTRAVE may cause serious side effects, including:**

**Seizures.** There is a risk of having a seizure when you take CONTRAVE. **If you have a seizure, stop taking CONTRAVE, tell you healthcare provider right away.**

**Risk of opioid overdose. Do not** take large amounts of opioids, including opioid-containing medicines, such as heroin or prescription pain pills, to try to overcome the opioid-blocking effects of naltrexone.
**Sudden opioid withdrawal.** Do not use any type of opioid **for at least 7 to 10 days before starting CONTRAVE.**

**Severe allergic reactions.** Stop taking CONTRAVE and get medical help immediately if you have any signs and symptoms of severe allergic reactions: rash, itching, hives, fever, swollen lymph glands, painful sores in your mouth or around your eyes, swelling of your lips or tongue, chest pain, or trouble breathing.

**Increases in blood pressure or heart rate.**

**Liver damage or hepatitis.** Stop taking CONTRAVE if you have any symptoms of liver problems: stomach area pain lasting more than a few days, dark urine, yellowing of the whites of your eyes, or tiredness.

**Manic episodes.**

**Visual problems (angle-closure glaucoma).** Signs and symptoms may include: eye pain, changes in vision, swelling or redness in or around the eye.

**Increased risk of low blood sugar (hypoglycemia) in people with type 2 diabetes mellitus who also take medicines to treat their diabetes (such as insulin or sulfonylureas).**
The most common side effects of CONTRAVE include nausea, constipation, headache, vomiting, dizziness, trouble sleeping, dry mouth, and diarrhea.
These are not all the possible side effects of CONTRAVE. Tell your healthcare provider about any side effect that bothers you or does not go away.

**Use of CONTRAVE**

CONTRAVE is a prescription weight-loss medicine that may help some adults with a body mass index (BMI) of 30 $kg/m^2$ or greater (obese), or adults with a BMI of 27 $kg/m^2$ or greater (overweight) with at least one weight-related medical problem such as high blood pressure, high cholesterol, or type 2 diabetes, lose weight and keep the weight off.

- CONTRAVE should be used with a reduced-calorie diet and increased physical activity

- It is not known if CONTRAVE changes your risk of heart problems or stroke or of death due to heart problems or stroke
- It is not known if CONTRAVE is safe and effective when taken with other prescription, over-the-counter, or herbal weight-loss products

CONTRAVE is not approved to treat depression or other mental illnesses, or to help people quit smoking (smoking cessation). One of the ingredients in CONTRAVE, bupropion, is the same ingredient in some other medicines used to treat depression and to help people quit smoking.

**Ask your doctor or healthcare professional if CONTRAVE is right for you. Please see Full Prescribing Information, includin Medication Guide, for CONTRAVE.**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

**Indication and Usage of MYSIMBA in the European Union**

MYSIMBA is indicated, as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index (BMI) of

- ≥ 30 kg/m2 (obese), or
- ≥ 27 kg/m2 to < 30 kg/m2 (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension)

Treatment with MYSIMBA should be discontinued after 16 weeks if patients have not lost at least 5% of their initial body weight.

**Please see Summary of Product Characteristics and more information about MYSIMBA for EU patients available at:** http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003687/human_med_001845.jsp&mid=WC0b01ac058001d124

Mysimba™ and Contrave ® are trademarks of Orexigen Therapeutics, Inc. registered with the U.S. Patent and Trademark Office.

**About Orexigen Therapeutics**

Orexigen Therapeutics, Inc. is a biopharmaceutical company focused on the treatment of obesity. Orexigen's first product, Contrave® (naltrexone HCl and bupropion HCl extended release), was approved in the United States in September 2014 and became the most prescribed branded obesity medication in the United States in June 2015. In the European Union, the drug has been approved under the brand name Mysimba® (naltrexone HCl/ bupropion HCl prolonged release). Orexigen is undertaking a range of development and commercialization activities, both on its own

and with strategic partners, to bring Contrave / Mysimba to patients around the world. Further information about Orexigen can be found at www.orexigen.com

**Forward-Looking Statements**

Orexigen cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "should," "intends," "potential," "suggests," "assuming," "designed" and similar expressions are intended to identify forward-looking statements. These statements are based on the Company's current beliefs and expectations. These forward-looking statements include statements regarding: the potential success of marketing and commercialization of Contrave/Mysimba in the United States and elsewhere; the potential growth of Contrave/Mysimba prescriptions; the potential for the Company to be profitable; the Company's strategic plans and initiatives including the Company's plans to expand its telemedicine pilot program; the potential for Orexigen and its partners to obtain regulatory approvals for and successfully commercialize Contrave and Mysimba in additional markets outside the United States; and the potential to maximize operational efficiencies by carefully managing operating expenses. The inclusion of forward-looking statements should not be regarded as a representation by Orexigen that any of its plans will be achieved. Actual results may differ materially from those expressed or implied in this release due to the risk and uncertainties inherent in the Orexigen business, including, without limitation: the potential that the marketing and commercialization of Contrave/Mysimba will not be successful, particularly, with respect to Contrave, in the U.S. following the launch of the patient-focused marketing campaign; the Company's ability to obtain and maintain partnerships and marketing authorization globally; our ability to adequately inform consumers about Contrave; our ability to successfully commercialize Contrave with a specialty sales force in the United States; our ability to successfully complete the post-marketing requirement studies for Contrave; the capabilities and performance of various third parties on which we rely for a number of activities related to the manufacture, development and commercialization of Contrave/Mysimba; the therapeutic and commercial value of Contrave/Mysimba; competition in the global obesity market, particularly from existing and generic therapies; the Company's failure to successfully acquire, develop and market additional product candidates or approved products; our ability to obtain and maintain global intellectual property protection for Contrave and Mysimba; legal or regulatory proceedings against Orexigen, as well as potential reputational harm, as a result of misleading public claims about Orexigen; our ability to maintain sufficient capital to fund our operations for the foreseeable future; the potential for a Delaware court to determine that one or more of the patents are not valid or that Actavis' proposed generic product is not infringing each of the patents at issue; and other risks described in Orexigen's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Orexigen undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. Further information regarding these and other risks will be included under the heading "Risk Factors" in Orexigen's Quarterly Report on Form 10-Q which we intend to file with the Securities and Exchange Commission on or about May 11, 2017

and its other reports, which are available from the SEC's website (www.sec.gov) and on Orexigen's website (www.orexigen.com) under the heading "Investors." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Source: Orexigen Therapeutics, Inc.

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Orexigen Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and par value amounts)

| | March 31, 2017 (Unaudited) | December 31, 2016 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 76,656 | $ 92,494 |
| Accounts receivable, net | 6,277 | 1,102 |
| Investment securities, available-for-sale | 9,985 | 11,499 |
| Restricted cash and investments | 40,000 | 90,005 |
| Inventory | 20,663 | 23,193 |
| Prepaid expenses and other current assets | 4,938 | 6,168 |
| Total current assets | 158,519 | 224,461 |
| Property and equipment, net | 927 | 1,044 |
| Intangible assets | 74,077 | 76,061 |
| Other long-term assets | 2,672 | 2,835 |
| Restricted cash | 188 | 188 |
| Total assets | $ 236,383 | $ 304,589 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 15,640 | $ 15,210 |
| Accrued expenses | 32,106 | 30,412 |
| Contingent consideration | — | 15,000 |
| Deferred revenue, current portion | 1,713 | 4,738 |
| Total current liabilities | 49,459 | 65,360 |
| Long-term contingent consideration | 8,200 | 6,800 |
| Long-term convertible debt | 24,701 | 64,279 |
| Long-term convertible debt, at fair value | 152,466 | 101,900 |
| Deferred revenue, less current portion | 6,069 | 5,863 |
| Commitments and contingencies | | |
| Series Z preferred stock, $.001 par value, 219,994 shares issued and outstanding at March 31, 2017 and December 31, 2016 | 3,343 | 3,343 |
| Stockholders' equity: | | |
| Preferred stock, $.001 par value, 10,000,000 shares authorized at March 31, 2017 and December 31, 2016; 219,994 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively | — | — |
| Common stock, $.001 par value, 300,000,000 shares authorized at March 31, 2017 and December 31, 2016; 15,227,802 and 14,616,751 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively | 15 | 15 |
| Additional paid-in capital | 703,933 | 698,229 |
| Accumulated other comprehensive income | 2,495 | 4,011 |
| Accumulated deficit | (714,298) | (645,211) |
| Total stockholders' equity (deficit) | (7,855) | 57,044 |
| Total liabilities and stockholders' equity (deficit) | $ 236,383 | $ 304,589 |

Orexigen Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2017 | 2016 |
| Revenues: | | |
| Net product sales | $ 19,041 | $ — |
| Collaborative agreement | 104 | 2,391 |
| Royalties | — | 2,642 |
| Total revenues | 19,145 | 5,033 |
| Cost of product sales | 6,187 | — |
| Operating expenses: | | |
| Research and development | 8,173 | 11,801 |
| Selling, general and administrative | 55,247 | 16,551 |
| Amortization expense of intangible assets | 1,984 | — |
| Change in fair value of contingent consideration | 1,400 | — |
| Total operating expenses | 66,804 | 28,352 |
| Loss from operations | (53,846) | (23,319) |
| Other income (expense): | | |
| Interest income | 147 | 123 |
| Interest expense | (1,173) | (1,936) |
| Change in fair value of financial instruments | (28,006) | — |
| Gain on extinguishment of debt | 12,316 | — |
| Foreign currency gain, net | 1,475 | 2,784 |
| Total other income (expense) | (15,241) | 971 |
| Net loss | $ (69,087) | $ (22,348) |
| Net loss per share - basic and diluted | $ (4.67) | $ (1.54) |
| Shares used in computing basic and diluted net loss per share | 14,806 | 14,556 |