
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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): August 1, 2019

Synthorx, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38756
(Commission
File Number)

46-4709185
(IRS Employer
Identification No.)

11099 N. Torrey Pines Road, Suite 190
La Jolla, California
(Address of Principal Executive Offices)

92037
(Zip Code)

Registrant's telephone number, including area code: **(858) 750-4789**

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:

- 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))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	THOR	The Nasdaq Global Select Market

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

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On August 1, 2019, Synthorx, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2019. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item and the exhibit attached hereto are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, whether filed before or after the date hereof and regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Synthorx, Inc. dated August 1, 2019

SIGNATURES

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

Synthorx, Inc.

/s/ Laura Shawver, Ph.D.

Laura Shawver, Ph.D.

President and Chief Executive Officer

Date: August 1, 2019



Synthorx Reports Second Quarter Financial Results

SAN DIEGO, CA – August 1, 2019 (GLOBE NEWSWIRE) -- Synthorx, Inc. (Nasdaq: THOR), a clinical-stage biotechnology company developing optimized therapeutics for cancer and autoimmune disorders, today reported financial results and provided a business update for the second quarter ended June 30, 2019.

“At Synthorx, we continue to leverage our Expanded Genetic Alphabet platform to rapidly develop a range of cytokine candidates with optimized properties against oncology and autoimmune targets,” said Laura Shawver, president and chief executive officer of Synthorx. “In recent months, we have made significant progress with the dosing of patients in Australia in the Phase 1/2 HAMMER trial of our lead candidate THOR-707, a ‘not-alpha’ Synthorin of IL-2, and FDA’s clearance of our investigational new drug application for THOR-707.”

Second Quarter 2019 and Other Recent Highlights

- **THOR-707 trial initiated:** In June, the company began dosing patients in HAMMER, a global, Phase 1/2, first-in-human clinical trial of THOR-707 in Australia. This is the first Synthorin™ developed from the Expanded Genetic Alphabet platform to enter the clinic. The Phase 1/2 single agent and combination arms of the trial will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and anti-tumor activity of THOR-707 in patients with advanced or metastatic solid tumors.
- **U.S. IND cleared for THOR-707:** In July, the U.S. Food and Drug Administration (FDA) cleared the investigational new drug (IND) application for THOR-707 in solid tumors, paving the way for enrollment in the U.S.
- **Presented preclinical data at ASCO Annual Meeting:** In June, Synthorx presented at the American Society of Clinical Oncology (ASCO) Annual Meeting its approach to utilizing its first-of-its-kind Expanded Genetic Alphabet platform technology to engineer IL-2 to improve its pharmacological profile. The preclinical data presented demonstrated the potential safety and anti-tumor effects of THOR-707.

Financial Results

For the second quarter ended June 30, 2019, Synthorx reported a net loss of \$12.4 million, compared to a net loss of \$4.0 million for the comparable period in 2018. For the six months ended June 30, 2019, the company reported a net loss of \$23.2 million, compared to a net loss of \$6.2 million for the comparable period in 2018.

Research and development (R&D) expenses for the second quarter ended June 30, 2019 were \$10.4 million, compared to \$3.4 million for the same period in 2018. For the six months ended June 30, 2019, R&D expenses were \$20.0 million, compared to \$5.2 million for the same period in 2018. The increase in the company’s R&D expenses for the 2019 periods are primarily attributable to the advancement of its THOR-707 program and related activities, including costs to develop its clinical supply manufacturing capabilities and clinical trial costs as it initiates its Phase 1/2 clinical study. Further, the company incurred

additional personnel and related costs as it has expanded its R&D team to support the development efforts for its programs.

General and administrative (G&A) expenses for the second quarter ended June 30, 2019 were \$3.0 million, compared to \$0.6 million for the same period in 2018. For the six months ended June 30, 2019, G&A expenses were \$5.4 million, compared to \$1.0 million for the same period in 2018. The increase in G&A expenses was primarily attributable to increased personnel and related costs as the company expanded its G&A team to support operations, including additional non-cash stock-based compensation cost of \$0.6 million and \$0.8 million for the three and six months ended June 30, 2019, as compared to the same periods in 2018. Furthermore, the company incurred additional costs in 2019 that were not incurred during the same period in 2018 as Synthorx now operates as a public company, including additional insurance, legal and accounting fees.

As of June 30, 2019, Synthorx reported cash, cash equivalents and investment securities of \$165.2 million, compared to \$188.4 million at December 31, 2018.

About Synthorx

Synthorx, Inc. is a clinical-stage biotechnology company focused on prolonging and improving the lives of people with cancer and autoimmune disorders. Synthorx' proprietary, first-of-its-kind Expanded Genetic Alphabet platform technology expands the genetic code by adding a new DNA base pair and is designed to create optimized biologics, referred to as Synthorins. A Synthorin is a protein optimized through incorporation of novel amino acids encoded by the new DNA base pair that enables site-specific modifications, which enhance the pharmacological properties of these therapeutics. The company's lead product candidate, THOR-707, a variant of interleukin-2 (IL-2), is in development in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor. The company was founded based on important discoveries at The Scripps Research Institute. Synthorx is headquartered in La Jolla, Calif. For more information, visit www.synthorx.com.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements related to: plans underlying THOR-707 clinical trials and development; preclinical data or plans underlying any of our other development programs; references to the development of our product candidates; the potential safety and efficacy of THOR-707 and our other product candidates; and the potential advantages of these drug programs. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Synthorx's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics and operating as a development stage company; Synthorx's ability to develop, initiate or complete preclinical studies and clinical trials for, obtain approvals for and commercialize any of its product candidates; changes in Synthorx's plans to develop and commercialize its product candidates; the potential for clinical trials of THOR-707 or any future clinical trials of other product candidates to differ from preliminary or expected results; Synthorx's ability to raise any additional funding it will need to continue to pursue its business and product development plans; regulatory developments in the United States and foreign countries; Synthorx's reliance on key third parties, including contract manufacturers and contract research organizations; Synthorx's ability to obtain and maintain intellectual property

protection for its product candidates; the loss of key scientific or management personnel; competition in the industry in which Synthorx operates; and market conditions. For a more detailed discussion of these and other factors, please refer to Synthorx'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. All forward-looking statements are qualified in their entirety by this cautionary statement and Synthorx undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

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SYNTHORX, INC.
STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Operating expenses:				
Research and development	\$ 10,425	\$ 3,387	\$ 19,989	\$ 5,152
General and administrative	3,040	602	5,395	1,027
Total operating expenses	<u>13,465</u>	<u>3,989</u>	<u>25,384</u>	<u>6,179</u>
Loss from operations	<u>(13,465)</u>	<u>(3,989)</u>	<u>(25,384)</u>	<u>(6,179)</u>
Other income (expense):				
Change in fair value of preferred stock purchase right liability	—	(14)	—	(14)
Interest income, net	1,095	—	2,163	—
Net loss	<u>\$ (12,370)</u>	<u>\$ (4,003)</u>	<u>\$ (23,221)</u>	<u>\$ (6,193)</u>
Net loss per common share, basic and diluted	<u>\$ (0.39)</u>	<u>\$ (4.21)</u>	<u>\$ (0.74)</u>	<u>\$ (6.54)</u>
Weighted average common shares outstanding, basic and diluted	<u>31,561,445</u>	<u>951,066</u>	<u>31,496,114</u>	<u>946,854</u>

SYNTHORX, INC.
BALANCE SHEETS
(in thousands)
(unaudited)

	June 30, 2019	December 31, 2018
Assets		
Current Assets:		
Cash, cash equivalents and investments	\$ 165,178	\$ 188,356
Prepaid expenses and other current assets	3,554	1,688
Total current assets	<u>168,732</u>	<u>190,044</u>
Operating lease right-of-use asset	3,003	—
Property and equipment, net	1,628	1,382
Other assets	30	80
Total assets	<u>\$ 173,393</u>	<u>\$ 191,506</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 884	\$ 2,228
Accrued liabilities	6,122	4,814
Lease liability, current	403	—
Total current liabilities	<u>7,409</u>	<u>7,042</u>
Lease liability, noncurrent	2,818	—
Deferred rent	-	104
Total liabilities	<u>10,227</u>	<u>7,146</u>
Stockholders' equity	<u>163,166</u>	<u>184,360</u>
Total liabilities and stockholders' equity	<u>\$ 173,393</u>	<u>\$ 191,506</u>