Idera Pharmaceuticals Reports Second Quarter 2018 Financial Results and Provides Corporate Update

August 2, 2018 8:30 PM EDT

Abstract accepted for 2018 European Society of Medical Oncology Annual Meeting

Cash runway into first quarter of 2020

EXTON, Pa., Aug. 02, 2018 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ: IDRA), a pharmaceutical company focused on the development and commercialization of its proprietary immune modulator, tilsotolimod, for the treatment of cancer, today reported its financial and operational results for the second quarter ended June 30, 2018.

“As we concluded the first half of 2018, we also arrived at a point of inflection for our company. Since my arrival at Idera, the company has undergone necessary significant changes as we evaluated numerous components of our portfolio, none of which were certain for success. After these nearly four years, it is now clear that any future success for Idera will be driven by our TLR9 agonist, tilsotolimod,” stated Vincent Milano, Idera’s Chief Executive Officer.

“The body of data that we have generated with tilsotolimod continues to demonstrate the potential positive difference this drug can make in patients who have not benefited from existing immuno-therapy. Our mission from here is to explore the entirety of the opportunity both in melanoma and additional tumor types in order that we can offer hope to as many patients as possible,” continued Milano.

“As it relates to the proposed merger that was recently terminated, we made an aggressive attempt to pursue a strategy that we believe would have strengthened our company, provided additional diversification and ultimately create more value for our shareholders. Throughout that process, my faith in the value of Idera and its future prospects has never wavered, nor will my belief in the approach of growing our company through business development activities. This will remain core for us moving forward as we continue to advance tilsotolimod, and at the same time search for additional assets to bring into Idera for our long-term success.”

Milano further added, “To our long-term shareholders, I understand that these have been challenging times. I’ve worked through these moments more than once during my career. I appreciate the loyalty you’ve shown our company and I assure you that your loyalty serves as a great motivator for our entire team to deliver success in the future.”

Clinical Development Program Updates:

ILLUMINATE (tilsotolimod) Clinical Development

ILLUMINATE 301 – Randomized Phase 3 trial of intratumoral tilsotolimod in combination with ipilimumab versus ipilimumab alone in patients with PD-1 refractory metastatic melanoma:

- Trial initiated in the first quarter of 2018;
- 26 of the planned 80 sites across 12 countries have been activated for the randomization of patients into the trial;
- Planned enrollment of approximately 300 patients with Overall Response Rate (“ORR”) and Overall Survival as primary endpoints; and
- U.S. Food and Drug Administration granted Fast Track Designation for tilsotolimod in combination with ipilimumab for the treatment of patients with unresectable or metastatic melanoma following failure of PD-1 inhibitor treatment in fourth quarter of 2017.

ILLUMINATE 204 – Phase 1/2 trial of intratumoral tilsotolimod in combination with ipilimumab or pembrolizumab in patients with PD-1 refractory metastatic melanoma:

Ipilimumab Combination Arm – Phase 2 Expansion Ongoing at RP2D of 8 mg

- Enrollment (up to 60 patients) completion expected by year end 2018;
- Recently increased trial sites open to enrollment to 8 (2 additional planned);
- Abstract accepted for the upcoming ESMO 2018 Congress meeting in Munich, Germany, October 20, 2018.

ILLUMINATE-204 Key Findings Presented at American Society of Clinical Oncology Meeting (ASCO 2018) (Date cut-off for safety: 4/09/18; Data cut-off for efficacy: 5/09/18):

- 21 patients treated with the 8 mg dose of tilsotolimod in combination with ipilimumab have had disease evaluations;
- Confirmed RECIST v1.1 responses (including 2 Complete Response [CR]) were observed in 8 of these 21 subjects (38.1%);
- Six of 8 responses are ongoing (1 CR ongoing for nearly 2 years); median duration of response for these 8 has not yet been reached;
- Overall 15 patients out of 21 evaluable for efficacy (71.4%) experienced disease control (CR, PR, or SD);
- The combination regimen is generally well tolerated. 6/26 subjects (23%) had immune-related toxicities indicating that IMO-2125 + ipilimumab does not appear to add toxicity versus ipilimumab alone;
- Injection-related toxicities were grade 1-2 transient fever and flu-like symptoms lasting <48 hours; and
- 15/26 patients (57.7%) with lesions accessible only by image-guided injection (5 deep visceral lesions and 10 lymph nodes) were included.

Pembrolizumab Combination Arm – Phase 1 Dose Escalation Ongoing - Update

- Enrollment in the last dosing cohort (32 mg) ongoing; and
- The previously reported partial response (PR) in 1 of the first 6 patients in the 16 mg cohort of intratumoral tilsotolimod in combination with pembrolizumab has evolved into a confirmed complete response (CR).

ILLUMINATE 101 – Phase 1b trial of intratumoral tilsotolimod monotherapy in patients with refractory solid tumors:

- Completed enrollment in first three dosing cohorts [11 patients treated with 8 mg dose of tilsotolimod, 8 patients treated with 16 mg dose of tilsotolimod, 8 patients treated with 23 mg dose of tilsotolimod; and enrollment continues in the final cohort (32 mg)];
- One patient in cohort 1 (8 mg) continues in follow-up; one patient in cohort 2 (16 mg) continues tilsotolimod monotherapy and one patient continues in follow-up; two patients in cohort 3 (23 mg) continue tilsotolimod therapy and two patients continue in follow-up. 6 of 8 planned patients for cohort 4 (32 mg) enrolled; and
- First patient enrolled into the refractory melanoma cohort continues at a dose of 8 mg of tilsotolimod as monotherapy.

Investigator Sponsored Trials (IST)

During the second quarter of 2018, the company announced that it had entered into a clinical development support agreement with Pillar Partners Foundation. Under the terms of the agreement, Pillar has agreed to provide direct funding to support three investigator initiated clinical trials to further strategically expand the clinical research of tilsotolimod. The three trials are:

- A Phase 1/2 open label study of intratumoral tilsotolimod in combination with intratumoral ipilimumab and IV nivolumab in a protocol open to multiple tumor types including non-small cell lung cancer (NSCLC), melanoma, squamous cell carcinoma of the head and neck and urothelial carcinoma. The principal investigator initiating this trial is Aurélien Marabelle, MD, PhD, Clinical Director of the Cancer Immunotherapy Program at Institut Gustave Roussy, Villejuif, France;
- A Phase 2 study of intratumoral tilsotolimod in combination with IV pembrolizumab in patients with NSCLC. The principal investigator initiating this trial is Arafat Tfayli, MD, Professor of Clinical Medicine, Director of Hematology/Oncology Fellowship Program at the American University of Beirut Medical Center (AUBMC), Lebanon; and
- A Phase 2 placebo-controlled study of intradermal administration of tilsotolimod in patients with T3/T4 primary melanoma scheduled to undergo a combined re-excision and sentinel

node biopsy (SNB) procedure. The principal investigators initiating this are Bas Koster, MD and Tanja de Gruijl, PhD at The VU University Medical Center, Amsterdam, the Netherlands.

Corporate Updates:
In July 2018, following an analysis of its gene-silencing technology platform and our research portfolio and the termination of the merger agreement, the company decided to suspend its rare disease and discovery programs as part of its overall strategy to more narrowly focus its capital resources on the development and commercialization of tilsotolimod. In connection with this focused strategy, it will be closing its facility at 167 Sidney Street in Cambridge, Massachusetts, with its Exton, Pennsylvania, location serving as its new headquarters.

On July 27, 2018, the Company implemented a 1-for-8 reverse split of its issued and outstanding shares of common stock (the Reverse Stock Split) and set the number of its authorized shares of common stock at 70,000,000. The Reverse Stock Split became effective on July 27, 2018 at 5:00 pm and the Company's common stock began trading on The Nasdaq Capital Market on a post-split basis at the open of trading on July 30, 2018. The Reverse Stock Split affected all of the company's stockholders uniformly and did not alter any stockholder's percentage interest in the company's equity, except to the extent that the Reverse Stock Split resulted in any of the Company's stockholders owning a fractional share, which will be settled in cash.

On January 21, 2018, the company entered into an Agreement and Plan of Merger (the Merger Agreement) with BioCryst Pharmaceuticals, Inc. (BioCryst), Nautilus Holdco, Inc., a direct, wholly owned subsidiary of BioCryst (Holdco), Island Merger Sub, Inc., a direct, wholly owned subsidiary of Holdco, and Boat Merger Sub, Inc., a direct, wholly owned subsidiary of Holdco. The board of directors of each of Idera and BioCryst unanimously approved the Merger Agreement and the transactions contemplated thereby and the required regulatory approvals were received. However, the proposed merger was subject to approval by the stockholders of Idera and BioCryst, and satisfaction of other customary closing conditions, as specified in the Merger Agreement.

At a special meeting of BioCryst stockholders held on July 10, 2018, BioCryst's stockholders voted against the adoption of the Merger Agreement. Following such vote and in accordance with the terms of the Merger Agreement, BioCryst terminated the Merger Agreement on July 10, 2018.

In accordance with the Merger Agreement, BioCryst paid the company a fixed expense reimbursement amount of $6 million in connection with the termination of the Merger Agreement.

Financial Results
Second Quarter Results
Net loss applicable to common stockholders for the three months ended June 30, 2018 was $16.0 million, or $0.59 per basic and diluted share, compared to net loss applicable to common stockholders of $21.5 million, or $1.15 per basic and diluted share, for the same period in 2017. Revenue in each of the three months ended June 30, 2018 and 2017 was nominal. Research and development expenses for the three months ended June 30, 2018 totaled $10.9 million compared to $17.9 million for the same period in 2017. General and administrative expense for the three months ended June 30, 2018 totaled $5.6 million compared to $3.9 million for the same period in 2017.

As of June 30, 2018, the company's cash and cash equivalents totaled $94.0 million. The company currently anticipates that, based on its current operating plan, its existing cash and cash equivalents, including the expense reimbursement proceeds received in July 2018 in connection with the termination of the Merger Agreement, will be sufficient to enable it to fund company operations into the first quarter of 2020.

About Idera Pharmaceuticals
Harnessing the approach of the earliest researchers in immunotherapy and Idera's experience in developing proprietary immunology technologies, Idera's lead development program is focused on priming the immune system to play a more powerful role in fighting cancer, ultimately increasing the number of people who can benefit from immunotherapy. Idera is committed to working with investigators and partners who share the common goal of addressing the unmet needs of patients suffering from difficult to treat, unmet cancers. To learn more about Idera, visit www.iderapharma.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, future operations, collaborations, cash resources, financial position, future revenues, projected costs, prospects, clinical trials, plans and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements, including whether the Company's cash resources will be sufficient to fund the Company's continuing operations and the further development of the Company's programs for the period anticipated; whether interim results from a clinical trial will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials will be indicative of the results that will be generated in future clinical trials; whether products based on the Company's technology will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful; and such other important factors set forth under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the period ended December 31, 2017 and in the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2018. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Idera Pharmaceuticals, Inc.
Condensed Statements of Operations
(In thousands, except per share data)

	Three Months Ended June 30,	Six Months Ended June 30,

	2018	2017	2018	2017
Alliance Revenue	$ 163	$ 187	$ 418	$ 565
Operating Expenses:				
Research and Development	10,880	17,891	24,436	29,376
General and Administrative	5,583	3,888	12,562	7,969
Total Operating Expenses	16,463	21,779	36,998	37,345
Loss from Operations	(16,300)	(21,592)	(36,580)	(36,780)
Other Income (Expense), Net	269	121	454	252
Net Loss	$ (16,031)	$ (21,471)	$ (36,126)	$ (36,528)
Net loss per common share applicable to common stockholders — Basic and Diluted	$ (0.59)	$ (1.15)	$ (1.39)	$ (1.96)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — Basic and Diluted	27,133	18,676	26,012	18,657

Idera Pharmaceuticals, Inc.
Condensed Balance Sheet Data
(In thousands)

	June 30, 2018	December 31, 2017
Cash, Cash Equivalents and Investments	$ 94,046	$ 112,629
Other Assets	5,468	5,788
Total Assets	$ 99,514	$ 118,417
Total Liabilities	$ 14,448	$ 10,722
Total Stockholders' Equity	85,066	107,695
Total Liabilities and Stockholders' Equity	$ 99,514	$ 118,417

Source: Idera Pharmaceuticals, Inc.

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Source: Idera Pharmaceuticals, Inc.