#### **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): August 11, 2015

# KURA ONCOLOGY, INC. (Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 000-53058 (Commission File Number)

61-1547851 (IRS Employer Identification No.)

11119 N. Torrey Pines Road, Suite 125, La Jolla, CA (Address of Principal Executive Offices)

92037 (Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 500-8800

(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))  |  |  |  |  |  |  |  |

#### Item 7.01 Regulation FD Disclosure.

Beginning on August 11, 2015, members of the management team of Kura Oncology, Inc. (the "Company") will be providing presentation materials (the "Presentation") to certain interested parties. A copy of the Presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information contained in this Current Report on Form 8-K and in the accompanying Exhibit 99.1 are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company, under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference. This Current Report on Form 8-K will not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is being disclosed pursuant to Regulation FD.

#### Item 9.01 Financial Statements and Exhibits.

| (A) | Exchibite |  |
|-----|-----------|--|
| 111 | Exhibits. |  |

| Exhibit<br>Number | Description                                   |  |
|-------------------|---|--|
| 99.1              | Presentation Materials of Kura Oncology, Inc. |  |

SIGNATURE

| Pursuant to the i          | equirements of the Securities E | Exchange Act of 1934, | the registrant has duly | caused this report to | be signed on its behalf by | y the undersigned |
|----------------------------|---------------------------------|-----------------------|-------------------------|-----------------------|----------------------------|-------------------|
| thereunto duly authorized. |                                 |                       |                         |                       |                            |                   |

KURA ONCOLOGY, INC.

 Date: August 11, 2015
 By: /s/ Annette North

 Annette North

Senior Vice President and General Counsel





Troy Wilson, Ph.D., J.D.
President and Chief Executive Officer
August 2015

### FORWARD-LOOKING STATEMENTS



This presentation contains forward-looking statements. Such statements include, but are not limited to, statements regarding our research and clinical development plans and projected timelines for tipifarnib, and our other programs, plans regarding regulatory filings, our expectations regarding the relative benefits of our product candidates versus competitive therapies, and our expectations regarding the therapeutic and commercial potential of our product candidates. The words "believe," "may," "will," "estimate," "plan", "continue," "anticipate," "intend," "expect," "potential" and similar expressions (including the negative thereof), are intended to identify forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of 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. For a discussion of the risks and other factors that may cause our actual results, performance or achievements to differ, please refer to our filings with the Securities and Exchange Commission. Our forward-looking statements in this presentation speak only as of the date this presentation is actually delivered by us in person. We assume no obligation or undertaking to update them for future events.



### **INVESTMENT SUMMARY**



#### Strategy

- Develop a diverse pipeline of targeted therapeutics for solid tumors and blood cancers
- Utilize precision medicine approach to identify patients most likely to benefit from treatments

### Development Approach

- Fast-to-market strategies in select patient subsets
- Expand development to broader indications after POC

### **Pipeline**

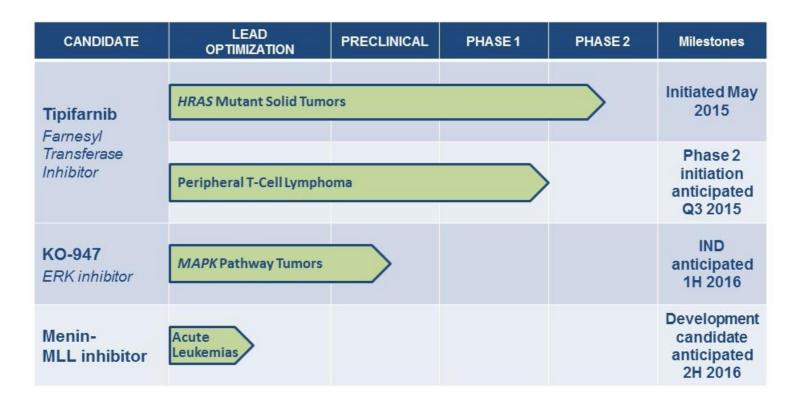
- Lead product candidate in Phase 2; 2<sup>nd</sup> Phase 2 trial planned Q3 2015
- Potential to initiate pivotal trials in 2017
- Preclinical programs advancing to clinic; anticipate IND 1H 2016

# Solid Financials

- \$60M private placement in March 2015 led by EcoR1 Capital
- Reverse merger completed Q1 2015
- · Seeking OTC quotation; potential for uplisting



## **DIVERSE DEVELOPMENT PIPELINE**

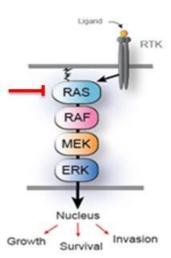




### TIPIFARNIB - LEAD PRODUCT CANDIDATE

- Licensed worldwide rights in oncology from Janssen; subject to ROFN
- Broad development program preceded advent of precision medicine; biomarker-based patient selection
  - Studied in > 5,000 patients across a diverse range of solid and liquid tumors
  - Generally well-tolerated at selected dose and schedule
  - ORRs range from < 10-40% in unselected populations</li>
  - Evidence of durable clinical benefit in patients
- Testing multiple hypotheses clinically to identify patient subsets to support approval
  - HRAS mutant solid tumors
  - Peripheral T-cell lymphoma (PTCL)
  - Evaluating additional indications for clinical development





# HRAS MUTATIONS ARE ENRICHED IN TUMORS

| TISSUE                    | HRAS MUTATION FREQUENCY |
|---------------------------|-------------------------|
| Salivary gland            | 15%                     |
| Urinary tract             | 11%                     |
| Cervix                    | 9%                      |
| Upper aerodigestive tract | 9%                      |
| Prostate                  | 6%                      |
| Skin                      | 6%                      |
| Stomach                   | 4%                      |
| Testis                    | 4%                      |
| Thyroid                   | 3%                      |
| Endocrine                 | 3%                      |
| Bone                      | 2%                      |
| Thymus                    | 2%                      |



Y. Pylayeva-Gupta, E. Grabocka & D. Bar-Sagi, *Nature Reviews Cancer* 2011, **11**, 761-774, reporting data from the COSMIC database.

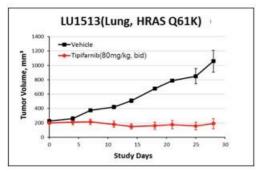
# TIPIFARNIB IS ACTIVE IN PATIENT-DERIVED MODELS OF HRAS MUTANT TUMORS

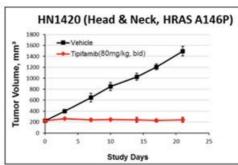
1200 600

fumor Volume, mm\*



- Tipifarnib is active and selective in patient-derived xenograft (PDX) models of HRAS mutant tumors; minimal activity in non-HRAS tumors (bottom panel)
- No approved drugs currently indicated to treat HRAS mutant tumors

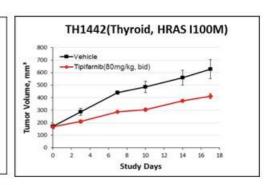




LU1868(Lung, HRAS wild type)

12 Study Days

- Tipifarnib (80mg/kg, bid)



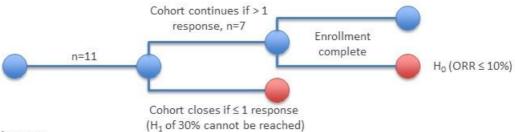


RURA

# TIPIFARNIB: ONGOING PHASE 2 STUDY IN *HRAS* MUTANT SOLID TUMORS



- Single arm, open-label, multi-centered study
  - Primary Endpoint: ORR measure by RECIST v1.1 criteria
  - Two patient cohorts
    - Cohort 1: Thyroid tumors with documented HRAS mutations (n=18)
    - Cohort 2: Solid tumors with documented HRAS mutations (n=18)



- Milestones
  - Study enrolling, first patient dosed May 2015
  - Topline data expected 2H 2016
  - If positive, potential to initiate pivotal study in 2017



# HIGH PHASE 2 ACTIVITY OF TIPIFARNIB HAS BEEN DEMONSTRATED IN T-CELL LYMPHOMAS



- Previous Phase 2 trial in relapsed/refractory lymphomas conducted at Mayo Clinic and U. Iowa
- High activity demonstrated in heavily pretreated patients with T-Cell and Hodgkin's Lymphoma<sup>1</sup>

| _3 // | 0            | R  | p.  | 31  | 0/    |
|-------|--------------|----|-----|-----|-------|
|       | $\mathbf{C}$ | 11 | 11. | -21 | - / ( |

| Disease Indication                | n  | CR<br>n (%) | PR<br>n (%) | ORR<br>(%) |
|-----------------------------------|----|-------------|-------------|------------|
| Overall                           | 36 | 6 (17)      | 5 (14)      | 31%        |
| Hodgkin Lymphoma                  | 19 | 2 (11)      | 2 (11)      | 21%        |
| Mycosis Fungoides                 | 4  | 0 (0)       | 2 (50)      | 50%        |
| Peripheral T-Cell Lymphoma        | 8  | 3 (38)      | 1 (13)      | 50%        |
| Anaplastic Large Cell<br>Lymphoma | 5  | 1 (20)      | 0 (0)       | 20%        |

- 81% of patients (29/36) had ≥ 4 prior therapies and 67% (24/36) prior SCT
- Safety findings across all patients (grade 3,4): 37% neutropenia, 31% thrombocytopenia, 11% anemia
- Potential to improve response rate, duration of response compared to approved 2<sup>nd</sup> line agents in PTCL



Witzig T. et al. Blood 2011; 118:4882-9; Ding H. et al. Blood 2011; 118:4872-81

# TIPIFARNIB – VISUAL EXAMPLES OF LESION CLEARING





Subcutaneous Panniculitis-like T-Cell Lymphoma (SPTCL)



Mycosis Fungoides (CTCL)

Witzig T. et al. Blood. 2011; 118:4882-9, Ding H. et al. Blood. 2011; 118:4872-81.



# TIPIFARNIB SHOWS ENCOURAGING ACTIVITY RELATIVE TO APPROVED AGENTS IN RELAPSED/REFRACTORY PTCL



|  | N               | Objective Response<br>Rate (%)                            | Median PFS / TTP<br>(months) | Median OS<br>(months) |
|--|-----------------|---|------------------------------|-----------------------|
| Beleodaq* (belinostat) for injection           | 1201,2          | 26  | 1.6                          | 7.9                   |
| (romidepsin) to repeated                       | 1301,2          | 25  | 4.0                          | 11.3                  |
| FOLOTYN 🙌                                      | 1091,2          | 27  | 3.5                          | 14.5                  |
|  |                 |   |                              |                       |
| Tipifarnib<br>(T-cell / Hodgkin's<br>Lymphoma) | 36 <sup>3</sup> | 31<br>(including 3 CRs and<br>1 PR in 8 PTCL<br>patients) | 3.2                          | 19.7                  |

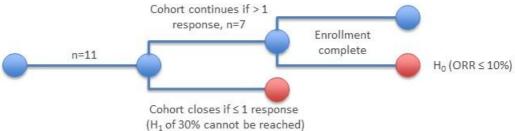
<sup>1. &</sup>lt;u>Drugs@FDA.gov</u>. 2.Mak *et al. J. Clin. Onc.* 31:1970-6 (2013) 3. Witzig *et al. Blood* 118:4882-9 (2011) Table lists data from separate studies; not head to head comparisons



## TIPIFARNIB: PLANNED PHASE 2 STUDY IN PTCL



- Single arm, open-label, multi-centered study
  - Primary Endpoint: ORR measure by International Workshop Criteria
  - Single patient cohort of n=18; potential for expansion to n=30



- Milestones
  - Planned start in Q3 2015
  - Topline data expected 1H 2017
  - If positive, potential to initiate pivotal study in 2017



### **TIPIFARNIB PHASE 2 TRIALS**



### Development Plans

- Ongoing Phase 2 study in HRAS mutant tumors
- · Planned Phase 2 study in Peripheral T-Cell Lymphoma
- Potential to support single-arm pivotal trials
- Evaluating additional indications for both company-sponsored and investigator-sponsored studies

# Anticipated Milestones

Initiate Phase 2 PTCL study
 Topline data: HRAS mutant tumors
 Topline data: PTCL
 Potential to initiate pivotal studies
 Q3 2015
 2H 2016
 1H 2017
 2017

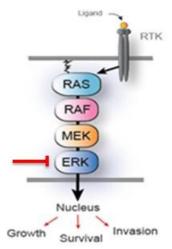
# U.S. Commercial Opportunity

- ~ 8,000 patient annual incidence of HRAS mutant cancers
- ~ 7,000-10,000 patient annual incidence of PTCL



## PRECLINICAL ERK INHIBITOR - KO-947

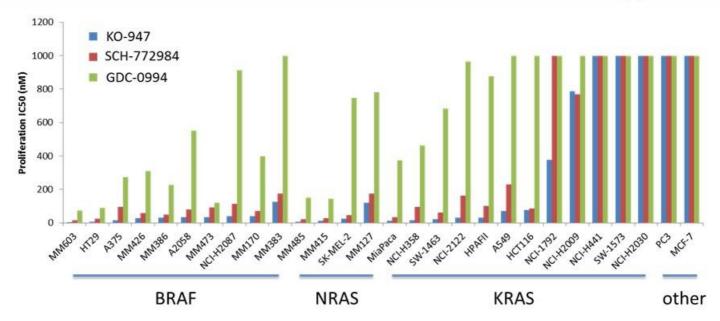
- Discovered and developed by Kura Oncology team at Araxes/Wellspring; acquired through asset purchase
- ATP active-site inhibitor of ERK
- Targets well-validated pathway that has led to multiple approved targeted oncology agents
- Aberrant signaling caused by activating mutations (KRAS, NRAS, BRAF) associated with numerous tumor types
- BRAF and MEK inhibitors have demonstrated high response rates, however, acquired resistance limits effectiveness
- Potential to address resistance mutations and other limitations of upstream targets





# KO-947 POTENTLY INHIBITS GROWTH OF CELL LINES WITH BRAF, NRAS AND KRAS MUTATIONS



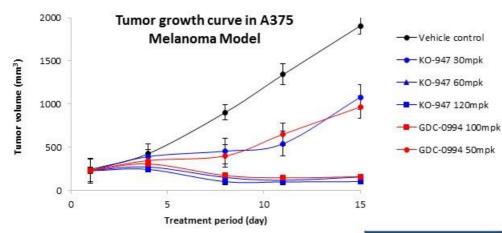


- KO-947 is more potent than Merck (SCH-772984) and Genentech (GDC-0994) compounds in cell lines with MAPK pathway activation due to BRAF, NRAS and KRAS mutations
- KO-947 is less active in non-MAPK activated cell lines



# KO-947 DISPLAYS STRONG ACTIVITY IN *BRAF* MUTANT MELANOMA MODELS





- KO-947 induced complete tumor regression at 60 mg/kg and is tolerated at 120 mg/kg
- KO-947 compares favorably to clinical-stage reference compound, GDC-0994

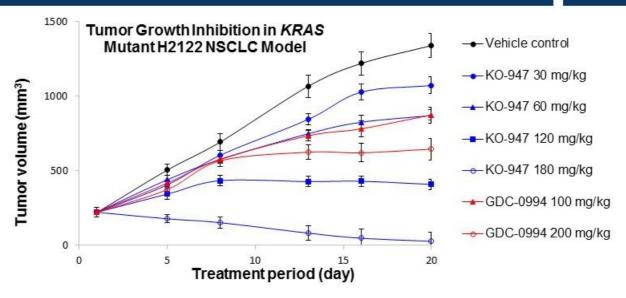
 KO-947 shows activity in melanoma cells with BRAF or NRAS mutations that are resistant to treatment with BRAF or MEK inhibitors

|             |       | IC <sub>50</sub> (nM) |          |
|-------------|-------|-----------------------|----------|
|             | A375  | NRAS                  | V600E    |
| Vemurafenib | 4,200 | > 10,000              | > 10,000 |
| Trametinib  | 7     | 77                    | 300      |
| GDC-0994    | 285   | 890                   | 760      |
| KO-947      | 58    | 116                   | 66       |



# KO-947 DISPLAYS ANTI-TUMOR ACTIVITY IN *KRAS* MUTANT NSCLC TUMOR MODELS





- KO-947 induced regression at 180 mg/kg in mouse lung tumor model with KRAS mutation, dose is tolerated in mouse; toxicology studies on-going
- Clinical-stage reference ERK inhibitor, GDC-0994, inhibited tumor growth about 50% at dose of 200 mg/kg



## KO-947: RATIONALE FOR FURTHER STUDY



**Development** • IND-enabling studies ongoing

Plans

Evaluating potential lead indications

Anticipated Milestones

IND submission

1H 2016

Initiate Phase 1 study

1H 2016

### U.S. Commercial Opportunity

BRAF mutant malignant melanoma annual incidence: 5,000

KRAS mutant tumors annual incidence

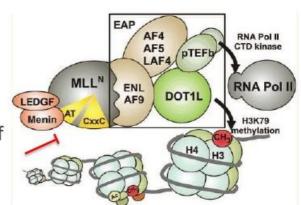
• Pancreatic cancer: 45,000 • Colorectal cancer: 53,000

· Non-small cell lung cancer: 23,000



### MENIN-MLL INHIBITOR PROGRAM

- Licensed worldwide rights from University of Michigan
- Chromosomal translocations of the MLL gene play a causative role in the onset, development and progression of a subset of acute leukemias
- Potential first-in-class program targeting the menin-MLL interaction for treatment of MLL-rearranged and MLL-PTD AML and ALL



- 3,200 patients with MLL-rearranged and MLL-PTD in the U.S.
- · Opportunities to target menin overexpression in additional tumor types

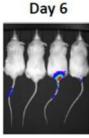


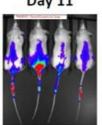
# IN VIVO ACTIVITY OF MENIN-MLL INHIBITORS IN MODELS OF DISSEMINATED LEUKEMIA



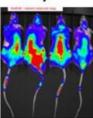
### Transplantation with MV4;11 (MLL-AF4)

Vehicle



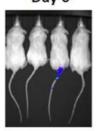


Day 14

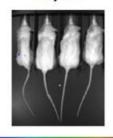


Day 6

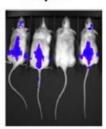
MI-503 (60 mg/kg)



Day 11



Day 14





0.4 0.6 0.8 0.2 radiance (\*107) [p/s/cm2/sr]

Leukemic cells denoted by bioluminescence

## **EXPERIENCED MANAGEMENT TEAM**





Yi Liu, Ph.D. Chief Scientific Officer

Pingda Ren, Ph.D. SVP, Chemistry and Pharm. Sciences

Antonio Gualberto, M.D., Ph.D. Chief Medical Officer

Heidi Henson, CPA Chief Financial Officer

Annette North, LLB SVP and General Counsel













## **BOARD AND ADVISORS**



#### **BOARD OF DIRECTORS**

Faheem Hasnain President and CEO, Receptos, Inc.

Robert Hoffman Chief Financial Officer, AnaptysBio, Inc.

Troy Wilson, Ph.D., J.D. President and CEO, Kura Oncology, Inc.

SCIENTIFIC ADVISORS

Kevan Shokat, Ph.D. Professor and Chairman, Dept. Cellular &

Molecular Pharmacology, UCSF

Frank McCormick, Ph.D., FRS Director Emeritus of the UCSF Helen Diller Cancer

Center and Professor, UCSF

Neal Rosen, M.D., Ph.D. Director of the Center for Molecular Therapeutics

at Memorial Sloan-Kettering Cancer Center

Sir Simon Campbell, CBE, FRS Former Senior VP Worldwide Discovery &

Medicinal R&D Europe at Pfizer



## SOLID FINANCIAL FOUNDATION



- Private Placement and Transition to Public Company
  - \$60 million raise led by EcoR1 Capital
    - Fidelity Management & Research Company
    - Arch Venture Partners
    - Boxer Capital of Tavistock Life Sciences
    - · Partner Fund Management
    - NextTech Invest
    - Includes conversion of \$7.5M convertible notes
  - Completed reverse merger to become public reporting company
- Upcoming Financial Events
  - Seeking OTC quotation
  - Potential for uplisting to NASDAQ or NYSE
- Q1/2015 cash balance: \$53.6 million



# DIVERSE PIPELINE WITH POTENTIAL FOR NEAR-TERM VALUE-CREATING MILESTONES



| PROGRAM    | EVENT   | ANTICIPATED<br>TIMING |
|------------|---|-----------------------|
| Tipifarnib | Initiate Phase 2 clinical trial in PTCL                               | Q3 2015               |
| KO-947     | IND submission  | 1H 2016               |
| KO-947     | Initiate Phase 1 clinical trial                                       | 1H 2016               |
| Tipifarnib | Topline data from Phase 2 clinical trial in <i>HRAS</i> mutant tumors | 2H 2016               |
| Menin-MLL  | Nomination of development candidate                                   | 2H 2016               |
| Tipifarnib | Topline data from Phase 2 clinical trial in PTCL                      | 1H 2017               |



### **INVESTMENT SUMMARY**



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