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Kineta, Inc. (KA: NASDAQ)

KA: Third Quarter Results

Kineta's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. Additionally, we apply a success probability of 15% for KVA12123 in solid tumor cancers which recognizes regulatory and commercialization risks. The model includes contributions from the United States and rest of world.

Current Price (11/6/2023)	$4.42
Valuation	**$13.50**

OUTLOOK

Kineta is a clinical-stage, oncology-focused biotechnology company targeting innate immune checkpoints in solid tumors. Its pipeline features two assets. Lead candidate KVA12123 is a Ph1/2 anti-VISTA mAb undergoing dose escalation and expansion studies. Asset two is an anti-CD27 mAb that is expected to begin clinical trials in late 2024.

Discovery efforts have produced KVA12123 and demonstrated its specificity to VISTA (V-domain Ig Suppressor of T cell Activation). Preclinical work shows activation of the immune system and anti-tumor response to the molecule as both mono- and combination therapy.

KVA12123 is expected to complete Ph2 trials in 2025, after which pivotal Ph3 trials will begin. BLA submission is expected in 2028 and commercialization in 2029. Ex-US sales are expected one year later. Grant of Fast Track may allow the use of surrogate endpoints and open eligibility for Accelerated Approval which could advance the timeline by two years.

While VISTA is not as prominent as other immune checkpoints, research has shown anti-VISTA's ability to limit tumor growth, especially in combination with other checkpoint inhibitors targeting PD-1 or CTLA-4. While initial clinical studies are broadly focused on solid tumors, OC, CRC and NSCLC are likely end targets for KVA12123.

SUMMARY DATA

52-Week High	**15.54**
52-Week Low	**1.78**
One-Year Return (%)	**55.3**
Beta	**0.9**
Average Daily Volume (sh)	**28,230**
Shares Outstanding (mil)	**11.2**
Market Capitalization ($mil)	**49.5**
Short Interest Ratio (days)	**2.1**
Institutional Ownership (%)	**3.4**
Insider Ownership (%)	**33.3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$0.4 A	$0.8 A	$0.2 A	$0.5 A	$2.0 A
2023	$0.3 A	$5.2 A	$0.0 A	$0.0 E	$5.4 E
2024					$0.0 E
2025					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2022	-$1.07 A	-$1.23 A	-$1.14 A	-$5.25 A	-$12.87 A
2023	-$0.77 A	$0.04 A	-$0.46 A	-$0.32 E	-$1.43 E
2024					-$1.41 E
2025					-$1.35 E

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WHAT'S NEW

3Q:23 Financial and Operational Results

Since our last report less than a month ago, Kineta, Inc. (NASDAQ: KA), has reported its third quarter financial and operational results, dosed its first combination therapy patient in its Phase I/II VISTA-101 clinical trial and presented two posters at SITC for its anti-CD27 and anti-VISTA monoclonal antibodies.

Highlights for 2023 include:

- VISTA as I-O target KOL event – March
- First monotherapy patient dosed in KVA12123 Phase I/II study – April
- $6 million direct offering priced – April
- Presented VISTA biomarker data and KVA12123 Phase I/II clinical trial update at AACR - April
- Addition to Russell Microcap Index – June
- Addition of new directors to board - June
- $5 million milestone announced from Merck - June
- Immuno-oncology webinar featuring Kineta CEO Shawn Iodonato – July
- Research agreement with Fred Hutchinson Cancer Center to evaluate VISTA biomarkers - September
- $3 million direct offering closed – October
- First combination therapy patient dosed in VISTA-101 clinical trial with KVA12123 – October
- Multiple presentations at SITC for KVA12123 & Anti-CD27 - November

Kineta generated no revenues during 3Q:23 and reported a net loss of ($5.4) million, or ($0.46) per share. For the quarter ending September 30, 2023 and versus the same period in the prior year:

- Revenues were $0 compared with $200,000 which were related to a National Institutes of Health (NIH) grant to research arenavirus hemorrhagic fever in a program that is now concluded;
- Research & Development expense totaled $1.9 million, down 27% from $2.6 million. The decline was attributable to substantially lower personnel costs due to reductions in R&D staff as the company transitioned to the clinic. This was partially offset by an increase in KVA12123 program costs and recognition of expenditures related to the ALS program;
- General & Administrative expenses were $2.1 million, up 2% from $2.0 million primarily due to higher personnel costs, professional services and other administrative expenses. Increases were generally attributable to public company costs;
- Total other income came from interest and investment sources. It declined on account of change in fair value of notes partially offset by less interest expense due to lower balances of interest paying notes;
- Net loss was ($5.4) million or ($0.46) per share compared with net loss of ($5.6) million or ($1.14) per share, respectively.[1]

At third quarter's end, marketable securities, cash and equivalents totaled $7.6 million. Operating cash burn for 3Q:23 was a paltry ($0.2) million on account of the settlement of the license receivable from Merck which was recorded as revenue in the second quarter. After September 30, Kineta raised a net $2.7 million from a registered direct offering. Effective control of cash expenditures has allowed the company to maintain access to the $22.5 million from the second closing of the private placement. The company expects to access these funds next year which should provide sufficient capital to fund operations until early 2025. Financing cash flows were minimal in 3Q:23.

[1] Prior year earnings per share are adjusted for the May 2023 reverse share split.

AACR Presentation of Anti-CD27 Preclinical Data

Dr. Thierry Guillaudeux, Kineta's Chief Scientific Officer presented a poster entitled CD27 is a New Promising T-cell Co-stimulatory Target for Cancer Immunotherapy at the American Association for Cancer Research (AACR) Special Conference on Tumor Immunology and Immunotherapy, on October 3, 2023 in Toronto, Ontario, Canada. The goal of the work summarized in the poster was to perform *in vitro* and *in vivo* assessments to identify an anti-CD27 agonist antibody lead candidate.

In summary, Kineta's leading monoclonal antibody (mAb) candidates showed high affinity binding to both human and cynomolgus monkey CD27, as well as high specificity against CD27, with no cross-reactivity detected against other members of the tumor necrosis factor receptor super family (TNFRSF). Additionally, none of the selected mAbs block the binding of CD27's natural ligand, CD70.

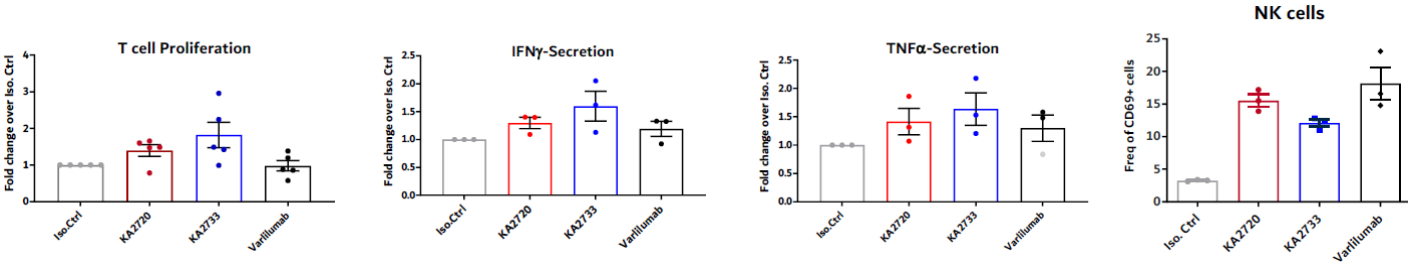
Investigators observed robust agonist properties related to T cell proliferation and activation after engagement of NFkB-mediated CD27 signaling as well as NK cell activation. The lead mAb showed antitumor efficacy *in vivo* in solid and hematological mouse tumor models as a single agent or in combination with other immunotherapies.

Society for Immunotherapy of Cancer's (SITC) 38th Annual Meeting Poster Summary

Anti-CD27

A November 3rd press release highlighted the presentation of Kineta's SITC poster which shared new data from the anti-CD27 monoclonal antibody program. The preclinical work showed that Kineta's anti-CD27 binds to human and monkey CD27, but not to the rat or mouse variant, indicating that the primate model is appropriate for further preclinical work. The molecule also shares a different binding side from CD70 on CD27, allowing for co-stimulation from other sources. Kineta's antibody drives strong T cell activation as well as natural killer (NK) cell activation, as shown in the following exhibit. It also demonstrates *in vivo* antitumor efficacy both as monotherapy or in combination with other immunotherapies such as anti-PD1 checkpoint inhibitors for both solid and hematological tumor models.

Exhibit I – Anti-CD27 Antibodies Activate T Cells & NK Cells[2]

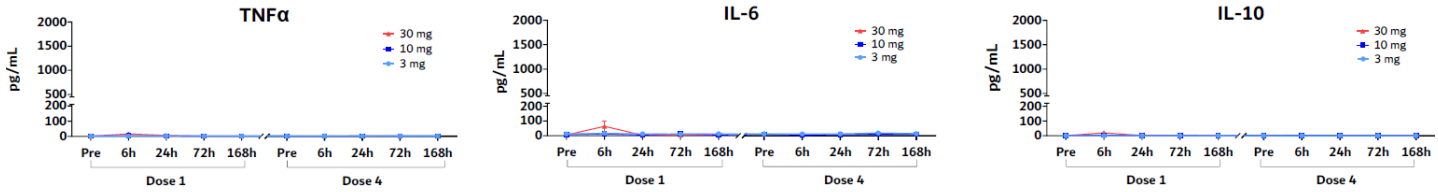


Anti-VISTA KVA12123

A November 6th press release highlighted Kineta's poster presentation of data for its Phase I/II monotherapy trial evaluating KVA12123, its VISTA blocking immunotherapy. This is the first look at the company's first clinical trial which evaluated 11 subjects with mostly late-stage disease who were administered KVA12123 in a twice-weekly infusion. Findings from the study included a greater than dose-proportional pharmacokinetic profile, greater than 90% receptor occupancy in the 30 mg dosing cohort and a strong signal from biomarkers including a variety of cytokines, chemokines, NK cells, CD4+ and CD8+ T cells. Three monotherapy cohorts were evaluated, including 3, 10 and 30 mg, establishing a clinical safety profile, favorable tolerability and no dose limiting toxicities. Cytokine release syndrome (CRS) was not observed. On-target changes in anti-tumor immune cell subpopulations were observed after treatment, demonstrating drug activity. Next steps for the study are to expand the monotherapy cohorts to 100, 300 and 1000 mg and move into combination work with pembrolizumab, which has already started. Further data is expected to be shared at an appropriate conference in spring of next year.

[2] Kineta poster presented at SITC 2023. CD27 is a new promising T-cell co-stimulatory target for cancer immunotherapy.

Exhibit II – No Evidence of CRS-Associated Cytokine Induction with KVA12123[3]

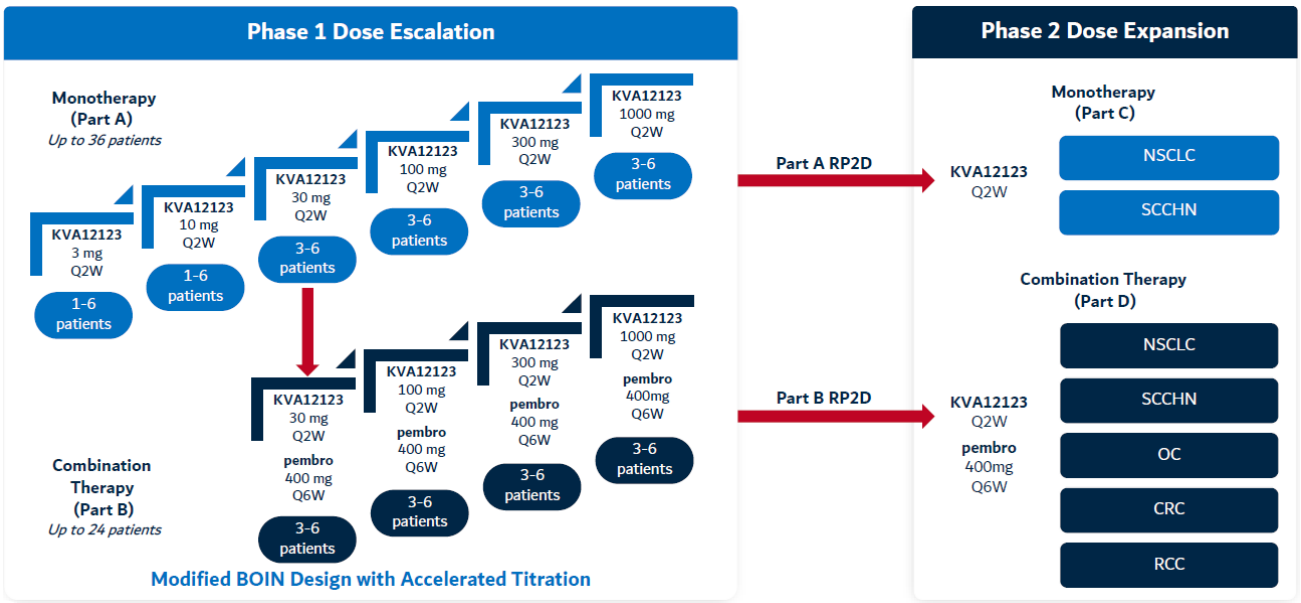


The following sections include additional background detail regarding the Phase I/II trial evaluating KVA12123.

KVA12123 Monotherapy Safety & Biomarker Data

An October 3rd press release outlined initial findings from Kineta's Phase I/II clinical trial evaluating KVA12123 in the VISTA-101 clinical trial. The first three monotherapy dose levels were evaluated and produced no dose limiting toxicities. The investigational therapy was well tolerated by subjects and no cytokine related adverse events were observed. KVA12123 produced a greater than dose proportional pharmacokinetic profile achieving greater than 90% VISTA receptor occupancy (RO) across subjects in the 30 mg dosing cohort.

Exhibit III – KVA12123 Clinical Trial Design[4]



The VISTA-101 trial enrolled 11 subjects with advanced solid tumors in the first three monotherapy dose-escalation cohorts, where subjects received either 3, 10 or 30 mg of KVA12123 by intravenous (IV) infusion every two weeks. Enrollees were heavily pretreated with multiple prior lines of therapy including chemotherapy, radiation, and immunotherapy. In the first three monotherapy cohorts, KVA12123 was well tolerated at all doses and no dose limiting toxicities (DLTs) were observed. Furthermore, as KVA12123 was engineered to mitigate adverse events associated with cytokine release syndrome (CRS), the study is closely monitoring proinflammatory cytokines that are associated with CRS (IL-6 and TNFα) in the Phase I portion of the study. No evidence of CRS or proinflammatory cytokine induction have been observed at any dose level with KVA12123 in the initial cohorts.

To develop the recommended Phase II dose, Kineta developed a proprietary assay to evaluate VISTA RO on immune cells from patients treated with KVA12123. Greater than 90% VISTA receptor occupancy was achieved at the 30 mg dose. Furthermore, pharmacokinetic analyses demonstrated a greater than dose-proportional increase in drug exposure across all evaluated doses, consistent with target-mediated drug disposition at lower doses. Kineta will continue escalating monotherapy dose cohorts of KVA12123 in Part A and has initiated Part B of the study to evaluate KVA12123 in combination with pembrolizumab. Initial monotherapy efficacy data were presented at SITC and discussed in the previous section.

[3] Kineta poster presented at SITC 2023. VISTA-101: A phase 1/2 clinical trial of KVA12123, an engineered IgG1 targeting VISTA alone and in combination with pembrolizumab in advanced solid tumors.
[4] Kineta April 2023 Corporate Presentation

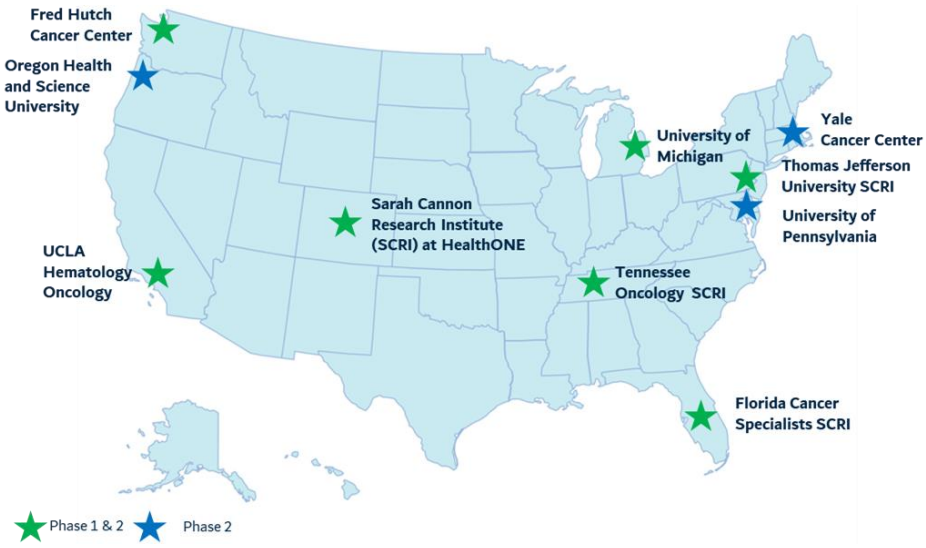
Background on the KVA12123 Clinical Study

Following the clearance of the investigational new drug (IND) application by the FDA in November 2022, Kineta began preparations for its Phase I/II clinical study evaluating KVA12123 as a single-agent and in combination with pembrolizumab in patients with advanced solid tumors. The initial timeline for the study called for a start to the trial before year-end 2022, which was achieved, and a report of interim results by late 2023 which was also accomplished. A summary of the trial has been posted on clinicaltrials.gov under NCT05708950.

Kineta is collaborating with Merck through the latter's contribution of pembrolizumab (Keytruda) to the alliance and seeks to determine the safety and efficacy of KVA12123 both alone and in combination with the PD-1 inhibitor pembrolizumab. Secondary endpoints include pharmacokinetics, immunogenicity, tumor response as per Immunotherapy Response Evaluation Criteria in Solid Tumors (iRECIST) standards and objective response rate (ORR). The study will be conducted in four parts: The first two will focus on dose escalation (single-agent and in combination), and the second two will focus on dose expansion (single-agent and in combination). Up to 10 dose escalation cohorts will be evaluated in Phase I and results will determine a recommended Phase II dose. Maximum tolerated dose will also be identified. Exploratory endpoints will examine receptor occupancy (RO), chemokine and cytokine levels in blood, immune cell populations in blood and VISTA expression in the tumor pre-and post-treatment.

Adult patients with advanced or metastatic solid tumors that have progressed or have been non-responsive to standard-of-care therapies are eligible to enroll. Up to 60 patients will be enrolled for the Phase I portion. Phase II will narrow the patient population primarily for non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), ovarian cancer (OC), colorectal cancer (CRC), renal cell carcinoma (RCC) and potentially other malignancies.

Exhibit IV – Phase I/II Clinical Research Sites[5]



On April 12th, the company announced that the first patient had been dosed and confirmed that initial data from the Phase I portion would be provided before the end of 2023. On April 17th, Kineta provided an update on the trial noting that tissue and serum samples would be collected to isolate predictive biomarkers.

To further develop the VISTA biomarker, Kineta entered into a research agreement with Fred Hutchinson Cancer Center in mid-September. The arrangement will evaluate VISTA expression as a potential biomarker in cancer patients from Kineta's ongoing Phase I/II clinical trial evaluating KVA12123, the company's VISTA blocking immunotherapy, alone and in combination with pembrolizumab.

The goal of the work is to evaluate VISTA expression as a biomarker to guide patient selection and treatment optimization for VISTA-targeted therapies. No standardized method exists for identifying patients that will respond well to anti-VISTA therapies. Development of a standardized evaluation of the marker may potentially inform the Phase II study design for KVA12123 and predict favorable responses to treatment. The screen is expected to be similar to the PD-L1 scoring method for using PD-1 / PD-L1 checkpoint inhibitors.

[5] Kineta corporate presentation, June 2023.

Kineta plans to pursue expedited pathways to approval, if available. Several regulatory routes allow for more rapid evaluation and approval of drug candidates. The company has identified Fast Track and Accelerated Approval as possible options. The FDA's Fast Track requires that a drug demonstrate the potential to address an unmet need for a serious condition. It provides several benefits to the sponsor including closer collaboration with the FDA, rolling review of the drug's Biologic License Application (BLA), eligibility for Accelerated Approval and Priority Review among other supportive measures. Accelerated Approval is a program intended for serious conditions that qualify as unmet medical needs. The pathway allows for surrogate endpoints to be used, which may greatly accelerate the clinical trial process. As a condition of accelerated approval, the sponsor is required to conduct post-marketing studies to confirm the anticipated clinical benefit.

These programs may allow Phase II data to be used to support a BLA and shorten the length of the trial by using objective response rate (ORR), progression-free survival (PFS) or other intermediate measures to evaluate efficacy. Using these endpoints would reduce the time required to evaluate efficacy as opposed to overall survival (OS), which is considered the most stringent standard for assessing clinical benefit. If a surrogate endpoint is used for provisional approval, OS will likely be required for the primary endpoints in confirmatory trials. To maintain a conservative stance, our estimates assume that Kineta will advance into Phase III trials after Phase II and will not benefit from an expedited pathway. Upon confirmation of either Fast Track or Accelerated Approval, we will adjust the model accordingly.

Our estimates call for the ongoing Phase I study to be fully enrolled by year-end 2023, followed by the start of the Phase II in 3Q 2024. We expect the Phase II to require 24 months to complete, followed by a Phase III in 2026 which would end in late 2027. A BLA is expected to be compiled and submitted to the FDA in 2028 and, if granted, approval and commercialization would come in 2029. For other regions around the world, we anticipate a one-year delay in the submission of a drug application, suggesting that additional regions will grant approval by 2030 and beyond. We discuss the details of our estimates further in the valuation section of our initiation report.

Capital Raise

On October 4th, Kineta announced a $3 million registered direct offering and that it had entered into a definitive agreement for the sale of 890,208 shares or pre-funded warrants at a price of $3.37/unit. 890,208 warrants with an exercise price of $3.25 were also issued along with the units with a duration of five- and one-half years. After the completion of the offering, Kineta issued 110,000 shares of common stock and 780,208 pre-funded warrants. On October 5th, Kineta closed the offering raising gross proceeds of $3 million and net proceeds of $2.7 million. HC Wainwright acted as the exclusive placement agent for the offering.

Upcoming Milestones

- Second closing of $22.5 million private placement – April 2024
- Additional mono and combination therapy data for KVA12123 – 2Q:24
- FDA end of Phase I meeting for KVA12123 – 3Q:24
- Initiate Phase II KVA12123 study – 3Q:24
- IND filing for anti-CD27 agonist – 4Q:24

Exhibit V – Upcoming Milestones[6]

Anticipated Milestones		2023		2024			
		3Q	4Q	1Q	2Q	3Q	4Q
KVA12123	Initial monotherapy safety data	●					
	Initial monotherapy efficacy data		●				
	Additional monotherapy safety and efficacy data				●		
	Initial combination therapy data				●		
	FDA end of Phase 1 meeting					●	
	Initiate Phase 2 clinical study					●	
αCD27 mAb	IND filing						●

[6] Kineta October 2023 Presentation

Summary

Kineta has been very active presenting at a number of investor and scientific conferences over the last few months. Much work has been accomplished in preparation for an eventual IND filing for the anti-CD27 candidate and initial data from the VISTA-101 trial has been presented. Both assets have generated data that supports their advancement to later stages of development. Work has continued on developing the protocol for the anticipated Phase II portion of the anti-VISTA candidate and a research agreement was signed with Fred Hutchinson Cancer Center in Seattle to evaluate VISTA expression as a biomarker for patient selection. A small capital raise also took place which added $3 million gross to the balance sheet. In the second quarter of 2024 we expect to receive an update on KVA12123 interim data for the higher dose monotherapy and combination with pembrolizumab.

Key reasons to own Kineta shares:

- **Developing KVA12123, a Phase I/II immune checkpoint, to treat solid tumors**
  - **Addresses mechanism of cancer immune resistance**
  - **Integrates innate and adaptive immune responses**
  - **Demonstrates synergies with checkpoint inhibitors (anti-PD-1/PD-L1/CTLA-4)**
- **KVA12123 offers a favorable treatment effect in specific populations**
  - **OC, CRC and NSCLC are high VISTA expressers**
  - **Patients developing resistance to CIs are high VISTA expressers**
- **KVA12123 may augment response rates when combined with existing checkpoint inhibitors**
- **Produces favorable safety profile with no evidence of cytokine release syndrome (CRS)**
  - **Antibody design with engineered Fc region to reduce immunogenicity**
- **Offers additional monoclonal antibody (mAb) assets in early stage development**
  - **Anti-CD27 agonist**
- **Maintains global rights to intellectual property**

KVA12123 adds another compelling entry into the immuno-oncology universe and has shown promising activity along with other checkpoint inhibitors in addressing high VISTA-expressing tumors. We maintain our valuation of $13.50 per share.

PROJECTED FINANCIALS

Kineta, Inc. - Income Statement

Kineta, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($USD)	**$1,953**	**$281**	**$5,161**	**$0**	**$0**	**$5,442**	**$0**	**$0**
Research & Development	$15,928	$2,843	$2,710	$1,909	$3,348	$10,810	$14,210	$14,870
General & Administrative	$8,696	$3,924	$3,431	$2,077	$1,800	$11,232	$9,889	$10,320
In-process R&D	$18,860	$0	$0	$0	$0	$0	$0	$0
Income from Operations	($41,531)	($6,486)	($980)	($3,986)	($5,148)	($16,600)	($24,099)	($25,190)
Other Items	($21,922)	$6	$1,355	($1,325)	($19)	$18	($50)	($50)
Non-controlling Interest	($45)	($29)	($11)	$69	($23)	$6	($105)	($114)
Pre-Tax Income	($63,408)	($6,451)	$386	($5,380)	($5,144)	($16,589)	($24,044)	($25,126)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	**($63,408)**	**($6,451)**	**$386**	**($5,380)**	**($5,144)**	**($16,589)**	**($24,044)**	**($25,126)**
Reported EPS	**($12.87)**	**($0.77)**	**$0.04**	**($0.46)**	**($0.32)**	**($1.43)**	**($1.41)**	**($1.35)**
Basic Shares Outstanding	4,926	8,361	9,939	11,738	16,250	11,572	17,100	18,550

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Kineta, Inc. – Share Price Chart[7]



[7] Price Chart courtesy of Barchart.com

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