## Initiating Coverage

February 25, 2015

| | |
|---|---|
| TICKER | NASDAQ: ARGS |
| RATING | BUY |
| PRICE TARGET | $13.00 |
| Price (February 24, 2015) | $8.98 |

# Argos Therapeutics, Inc.

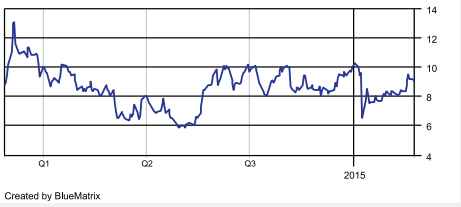
*Initiating Coverage with a Buy Rating and $13 PT*

| Market Data | |
|---|---|
| Market Cap (M): | $176.5 |
| Shares out (M): | 19.7 |
| Float (M): | 8.8 |
| Daily Vol, 3 Mo Avg (M): | 0.1 |
| 52-Week Range: | $13.74-$5.61 |
| Cash & Cash Eq (M): | $69.5 |
| Debt (M): | $22.2 |
| NAV (M): | NA |

| Financial Metrics | |
|---|---|
| Short Interest (M): | 0.6 |
| Instit. Holdings (%): | 79.4% |
| Cash Burn (M): | $28.3 |
| Short Interest (% of Float): | 7.2% |

| EPS | 1Q | 2Q | 3Q | 4Q | FY |
|---|---|---|---|---|---|
| 2014 | -1.05A | -0.61A | -0.77A | -0.82E | -2.75E |
| 2015 | -0.66E | -0.66E | -0.76E | -0.72E | -2.81E |
| 2016 | — | — | — | — | -2.50E |

1-Year Price History

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We initiate coverage on ARGS with a Buy rating and $13 price target. ARGS's proprietary Arcelis process uses the patient's immune system to target the disease unique to the patient. ARGS has two product candidates in the clinic for oncology and infectious disease, and we believe lead candidate AGS-003 can show a survival benefit in the ongoing pivotal ADAPT trial in metastatic renal cell cancer (mRCC) to support regulatory approval in 2017. Given available data, we assign a 55% probability of AGS-003 reaching the US market vs the 35% we believe is priced into the stock, representing 40% upside. We think the stock is worth $20 on US and $30 on global approvals. If the ongoing pivotal trial were to fail, we think AGS-003 would be delayed 2 years, and the stock could sell off to $6. Thus, we believe ARGS offers an attractive risk-reward skew for longer term investors.

**AGS-003 Looks Effective in Phase 2 Studies.** In a multi-center, open-label trial of Sutent + AGS-003 in 21 patients with intermediate- to poor-risk clear cell mRCC, the median overall survival (mOS) was 30.2 months. Among the 11 intermediate-risk patients, the mOS was 57.1 months, nearly double that expected in this patient population. Importantly, generating new, tumor-specific memory T cells after 5 doses of AGS-003 correlated with prolonged survival. We are cautiously optimistic this result can be replicated in the ongoing randomized Phase 3 trial.

**Phase 3 ADAPT Trial Is Under SPA and to Complete Enrollment in 1H15.** Conducted under a Special Protocol Assessment (SPA) with FDA, the pivotal trial in 450 newly diagnosed, intermediate- to poor-risk mRCC patients is designed to test the current standard-of-care, Sutent, vs Sutent + AGS-003. ADAPT incorporated changes from the Phase 2 trial which we think will help show AGS-003 benefit. These include enrolling more intermediate vs poor risk patients and excluding patients unlikely to receive 5 doses of AGS-003. While ADAPT is on track to complete enrollment and first interim analysis in 1H15, we believe a survival benefit is unlikely to reach significance until the third interim analysis in 2H16.

**Personalized Immunotherapy Is Cash Intensive; Incorporating Lessons from Provenge.** Although personalized immunotherapy requires a hefty upfront investment in manufacturing and logistics, we believe ARGS learned from the shortcomings of Provenge, the first FDA-approved personalized immunotherapy. Unlike Provenge, AGS-003 has a 2-week shelf life, eliminating the need for geographically selected manufacturing plants. Furthermore, Argos has instituted systems and designed disposables to allow automated and closed-system manufacturing. Overall, we think these measures enable acceptable COGS.

**Cash and Valuation.** At 9/30, ARGS had $69.5M in cash. ARGS will need additional equity and debt financing to launch AGS-003. ARGS needs to finance ~$45M to fund its manufacturing plant and ~$35M of production equipment. ARGS will also need to raise $260M+ to fund operations through 2019. Given the available data, we assign AGS-003 a 55% probability of reaching the market. At peak, we expect AGS-003 can reach 25% of the addressable US mRCC patients and generate ~$400M peak sales, representing net present value of $8/share. Ex-US, given its earlier stage of development, we assign a 35% probability of success and estimate AGS-003 can reach 20% of the EU addressable and 25% of the Japanese addressable markets, corresponding to ~$350M peak sales, or $5/share.

**INVESTMENT THESIS**

We initiate coverage on ARGS with a Buy rating and $13 price target. ARGS's Arcelis treats disease using the patient's own immune systems to target genetic mutations specific to the patient's own disease. With two product candidates already in the clinic for oncology and infectious disease, we think the ARGS platform is viewed cautiously pending validating data from a large randomized clinical trial, which we think likely could come in 2H16. Given the sparse data, we are cautiously optimistic that lead product candidate AGS-003 can show a survival benefit in the ongoing pivotal ADAPT trial in metastatic renal cell cancer (mRCC).

**Phase 3 AGS-003 Pivotal Trial to Complete Enrollment and First Interim Analysis in 2Q15.** Lead drug candidate AGS-003 is currently being tested in newly diagnosed intermediate- and poor-risk mRCC in combination with the current standard-of-care Sutent vs Sutent alone in the Phase 3 ADAPT trial. We note the trial is conducted under a Special Protocol Assessment (SPA) with the FDA which specifies a clinical hurdle of a Hazard Ratio (HR) of 0.708. ADAPT is on track to complete enrollment and reach its first interim analysis at ~25% events in 2Q15. However, we would be surprised if the difference in survival between the two arms at this early interim analysis sufficed to end the trial. We think that this endpoint will more likely be reached in 2H16 when the event rate is expected to reach 75%.

**AGS-003 Looks Effective in Small Phase 2 Trial Composed of Similar Population as Pivotal ADAPT Trial Patients.** A prior Phase 2 multi-center, open-label trial of Sutent + AGS-003 in 21 patients with intermediate- to poor-risk, clear cell mRCC showed impressive survival which was roughly double that expected for the trial population. With all the caveats of cross trial comparisons, we believe the patient populations are sufficiently similar between the Phase 2 and 3 trials and that ARGS has enriched the Phase 3 population for patients more likely to respond to AGS-003. In particular, ARGS has explicitly required a higher proportion of intermediate vs poor-risk patients (3:1 vs the 1:1 ratio in the Phase 2). Additionally, patients deemed unlikely to live 6 months, and thereby unlikely to receive 5 doses of AGS-003, are excluded by the surgeons. Taken together, we are cautiously optimistic that AGS-003 can show a survival benefit at the third interim analysis for ADAPT in 2H16, providing the basis for regulatory approval in 2017.

**Phase 2 AGS-004 for Pediatric and Adult HIV Eradication Remains Upside to Our Estimates.** Though AGS-004 is currently in Phase 2a trials in the pediatric and adult settings, we do not ascribe any valuation to this program pending a clear path to approval given the well-established and well-entrenched HIV treatment protocols. Like AGS-003, AGS-004 also generates the memory T-cells that correlate with prolonged overall survival in the AGS-003 mRCC program, providing additional comfort in our confidence for the AGS-003 program. Additionally, AGS-004 safety profile shows that the ARGS platform has an impeccable adverse event profile.

**Cash Intensive Business Model.** At September 30, 2014, ARGS had approximately $69.5 million in cash and equivalents on hand. We believe that ARGS will need additional equity and debt financing to launch what will initially be a capital intensive business. We estimate ARGS will need to raise $42-47 million for the manufacturing physical plant, an additional $35 million for AGS-003 production equipment sufficient to service the first 2,500 patients in the US and EU, and $260 million to fund operations through 2019 when we anticipate the Company will become cash flow positive.

**Valuation.** We derive a value of $13/share based on a sum-of-the-parts analysis, whereby we value each drug candidate based on a discounted earnings forecast. Specifically, we value AGS-003 (for mRCC) as a wholly-owned asset in the US and EU, and as a royalty stream for Japan. Our valuation does not include AGS-004 for HIV and also excludes cash.

**AGS-003 Represents Entire $13 Valuation.** We estimate AGS-003 has a 55% chance of reaching the US market and generating peak $411 million in sales, representing $8/share valuation to our probability-adjusted SOTP analysis. In Europe and Japan, where there is less clarity on a regulatory path forward, we assign a lower 35% probability of reaching the market and generating peak $352 million sales, representing $5/share valuation to our probability-adjusted SOTP analysis. As Medinet has a license to AGS-003 in Japan and ARGS is entitled to receive a single-digit royalty on sales, Japan represents $0/share in our SOTP valuation.

**Bear Case: $6 on ADAPT Trial Failure and Two-Year Regulatory Delay.** Should AGS-003 fail to show a statistically significant survival benefit in clear cell mRCC patients, we think the 450-patient Phase 3 trial would yield sufficient data for ARGS to

design and conduct a subsequent successful Phase 3 trial. Thus, we would expect the potential approval timeline to be shifted out to 2019 and an additional $165 million in additional operating expense to be financed through equity raises. Leaving the probabilities and our market estimates intact, this would represent $6/share valuation to the stock which we believe is the bear case scenario.

**Bull Case Scenarios: $20 on US and $30 on Global Approvals**

On US approval and making no changes to our market model, we would adjust our probability assumption to 100%, increasing the US portion of our AGS-003 SOTP valuation from $8/share to $14/share, resulting in an overall ARGS company valuation increase to $20/share. On subsequent EU approval, adjusting our probability assumption to 100% and leaving our market model assumptions intact, our EU AGS-003 valuation increases from $5/share to $15/share, resulting in an ARGS company valuation increase to $30/share.

**Rating Rationale**

Our Buy rating is based on our view that the Arcelis technology enabling personalized immunotherapy is an attractive asset that can be clinically and commercially successful. We estimate lead product candidate AGS-003 is worth $13/share based on a 55% cumulative probability of reaching the market and peak global revenues of $750 million in 2029. We currently do not include valuation for the HIV program, pending clinical proof-of-concept and a clear path to regulatory approval and commercial adoption. Our valuation also excludes $1/share in cash on hand.

**CATALYSTS**

| Timing | Drug | Milestone |
|---|---|---|
| 2/28/2015 | AGS-003 | Ph3 ADAPT trial -status update at ASCO GU |
| 2Q15 | AGS-003 | Ph3 ADAPT trial -last patient randomized |
| 1H15 | AGS-003 | Ph2a -initiate trial in additional indication |
| 1H15 | AGS-004 | Ph 2 -initiate combination therapy trial |
| 2Q15 | AGS-003 | Ph 3 ADAPT trial -status update at ASCO |
| 2H15 | AGS-003 | Feasibility trial -results of sampling from metastases |
| 2H15 | AGS-003 | Ph 2 trial -initiate with immune checkpoint inhibitor combo |
| 4Q15 | AGS-003 | Ph 3 ADAPT trial -interim report |

*Sources: Company reports and MLV & Co. estimates.*

**BACKGROUND**

**The Role of Dendritic Cells in Immunity.** The immune system patrols the body, surveying cells for signs of stress or foreign antigens that indicate the presence of infection or malignancy. The immune system is composed of an innate branch, which responds to conserved molecular motifs that are indicative of disease, and an adaptive branch that is able to respond to a nearly infinite number of foreign antigens. The innate branch plays an important role in early, non-specific disease responses while the adaptive branch is disease-specific and takes a couple weeks to develop and months to fully mature.

*Dendritic cells are master regulators of the immune system.*

Dendritic cells are master regulators that bridge the innate and adaptive arms of the immune system. They reside throughout the body and constantly sample the physiological environment, taking up antigens and monitoring for danger signals. When they encounter a stimulus, such as bacterial cell wall, viral RNA, or stress markers expressed on tumors, the danger signal causes the dendritic cells to mature and activate. Activated dendritic cells leave the periphery and migrate to lymphoid tissues, where they begin to produce pro-inflammatory stimuli and seek out T-cells, which are part of the adaptive immune system. The dendritic cells present the repertoire of antigens which they took up at the site of injury, trying to find a cognate T-cell that will respond to one of the antigens. If a T-cell recognizes an antigen presented by the dendritic cell, the two cells will bind each other and express a series of costimulatory signals, including CD28 and CD40. These costimulatory molecules induce the dendritic cell to mature and liberate the T-cell to initiate an adaptive immune response. **Dendritic cells are thus critical for instigating immune responses. ARGS's Arcelis Platform uses these master regulators to elicit T-cell mediated anti-tumor responses.**

*Dendritic cells prime cytotoxic T-cells, which are critical mediators of anti-tumor responses.*

There are two major classes of T-cells. Helper T-cells express the cell marker CD4 and play an important role in orchestrating adaptive immunity, especially by encouraging B-cells to produce antibodies. Cytotoxic T-cells express CD8 on their surface and play a crucial role in destroying malignant cells and cells that are infected with intracellular pathogens. If a CD8+ T-cell becomes activated by a dendritic cell presenting a mutated tumor protein, it first proliferates, making many copies of itself that then mature into differentiated T-cells. Some will become cytotoxic T-cells that produce effector molecules such as perforin, granzyme-B and granulysin. These T-cells will leave the

lymph node, search for tumor cells and destroy them. Other copies will become memory T-cells, which are important for long term immunity.

*Cancers acquire mutations that make them resistant to elimination by the immune system.*

**Cancers Evolve to Evade the Immune Response.** Pre-cancerous cells must acquire a number of mutations before they become malignant. One important category of mutations are those that allow cancer cells to evade immune elimination. Some of these disregulated genes act through direct contact with effector cells of the immune system. For example some cancers over-express one of the ligands for Programmed cell Death-1 (PD-1) which is expressed on effector T-cells. When PD-1 is bound by its ligand, it causes the T-cells to die or become unresponsive. Other factors, such as Interleukin-10 (IL-10), Vascular Endothelial Growth Factor (VEGF) and transforming growth factor-beta (TGF-$\beta$), are secreted by tumors and induce a more generalized immunosuppressive state. VEGF has been demonstrated to play a role in recruiting regulatory T-cells ($T_{REG}$) to the tumor. This T-cell population suppresses immune responses. Impaired dendritic cell function has also been described in a number of cancers including renal cell carcinoma, squamous cell cancer, and colorectal cancer (Cabillic, 2006; Legitimo, 2015).

## ARCELIS PLATFORM

*The Arcelis Platform harnesses the patient's own dendritic cells to elicit anti-tumor responses.*

The Arcelis Platform seeks to circumvent the immunosuppressive environment found in cancer patients by taking monocytes (dendritic cell precursors) from the patient and maturing them in culture. The Arcelis Platform also transforms the dendritic cells with CD40-ligand, a co-stimulatory molecule that helps keep the dendritic cells active when they are returned back to the immunosuppressive context of the patient. The platform consists of 6 basic steps:

1) Patient tumor sample is shipped to a centralized processing facility.
2) RNA is extracted and amplified. The RNA contains the repertoire of all the mutated genes that are expressed in the patient's tumor.
3) Monocytes are harvested from the patient's blood, in a widely available application known as leukapheresis, and shipped to the centralized processing facility.
4) Monocytes are matured into dendritic cells and loaded with the patient RNA as well as costimulatory molecules that will activate the dendritic cells.

5) Vials of the RNA loaded dendritic cells are frozen for future use.
6) The patient is immunized with 8 doses of the activated dendritic cells in the first year and receives booster shots thereafter.

The Arcelis Platform is well suited to slower growing cancers or cancers that are diagnosed early, such as bladder, non-small cell lung cancer, breast and colon, for which there is sufficient time to generate a successful immune response. Because it acts to restore immune function, the platform also has the potential to address other immunosuppressive diseases. Indeed, Phase 2 clinical trials focused on HIV elimination and eradication in adult and pediatric patients with AGS-004 are ongoing. The HIV program is fully funded by non-dilutive government grants.

**Differentiated from Other Immunotherapies**

*The Arcelis Platform primes the immune system with antigens that are specific to the patient's tumor.*

First, the Arcelis Platform is truly personalized to the individual tumor. The Arcelis Platform uses antigen presenting dendritic cells harvested from the patient, loads them with tumor antigens derived from the patient's tumor, and then returns them to the patient to elicit an anti-tumor response. Other cell based immune-therapies in the cancer space, such as CAR-T cells or sipuleucel-T, target a general tissue type (such as all cells expressing CD19 or prostatic acid phosphatase). These approaches essentially elicit an autoimmune response and can only be used for treating conditions in which the destruction of the tissue type is not life-threatening.

*The Arcelis Platform generates new cytotoxic T-cells to combat cancer.*

Second, the Arcelis Platform targets the first stage in overcoming cancer-induced immunosuppression. It generates a fresh population of antigen specific T-cells. Therapies that block immune checkpoint inhibitors, such as Opdivo (nivolumab) and Keytruda (pembrolizumab), which bind to PD-1, are targeting a later checkpoint and block immunosuppressive signals that are exerted directly by cancer cells on effector T-cells. Thus, there is a potential for synergy between Arcelis and these checkpoint inhibitors.

*The Arcelis Platform potentially provides broad protection against a large range of tumor antigens.*

Third, the Arcelis Platform targets the full repertoire of mutated proteins in the tumor and potentially confers long-term resistance. Antibodies and antibody-based therapies only target a single epitope. Generally, antibody therapies are not curative and must be re-administered periodically. Residual cancer can pick up mutations in the targeted epitope and develop

resistance to the therapy.

*The Arcelis Platform is adaptable to many cancer types.*

Fourth, because the Arcelis Platform is target-agnostic, it can potentially address a broad range of cancers without being re-tested for safety each time. In contrast, therapies that use chimeric antigen receptors or T-cell Receptors must be evaluated for clinical safety and efficacy with each target change.

## LEAD PRODUCT CANDIDATE AGS-003 IS IN PIVOTAL TRIAL

### AGS-003 Trials in Metastatic Renal Cell Carcinoma (mRCC)

*ARGS is pursuing metastatic renal cell carcinoma (mRCC) for its lead program.*

ARGS's lead candidate, AGS-003, is currently in a Phase 3 trial with newly diagnosed poor to intermediate-risk mRCC. AGS-003 was also tested as monotherapy in a Phase 1/2 trial and in combination with sunitinib in a Phase 2 trial. At the time the Phase 1 trial was initiated, standard front-line therapy was nephrectomy and Interferon-γ treatment. Currently, the National Comprehensive Cancer Network (NCCN) recommends nephrectomy and treatment with VEGF inhibitors, including Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab).

### Phase 1/2 AGS-003 Monotherapy Trial

*A Phase 1/2 monotherapy trial established the safety of AGS-003 and demonstrated signs of efficacy as well.*

The Phase 1/2 monotherapy trial established the safety of AGS-003 and showed early signs of efficacy. Investigators observed no Grade 3/4 adverse events in any of the 22 patients. The most common adverse event was injection site reaction with 15 patients (68%) exhibiting redness at the injection site. Four patients (18%) had injection site swelling, and another four experienced itching. Two patients also exhibited lymph node swelling and/or flu-like symptoms.

In the Phase 1/2 trial, 1 patient demonstrated a partial response (PR) and 7 patients (35%) exhibited stable disease (SD). The progression free survival (PFS) was 5.6 months for intermediate-risk patients (n=12) and 5.5 months for poor-risk patients (n=8). While there was no control arm for this trial, studies with Interferon-γ treated patients have demonstrated a PFS of 5.1 months and 2.5 months for intermediate and poor-risk patients respectively (Motzer, 2002). Though PFS seemed unremarkable, the median OS for AGS-003-treated patients was 18.5 months. For comparison, OS was 10 months and 4 months for intermediate and poor-risk patients in a subgroup analysis of

patients treated in clinical trials prior to the introduction of targeted therapies (Motzer, 1999). This suggests that AGS-003 substantially improved the OS of the treated patients. It is worth noting that other immunotherapies such as sipuleucel-T and ipilimumab were approved on overall survival benefit despite having only modest effects on objective response rates and PFS.

**Phase 2 AGS-003 + Sutent Trial**

*The Phase 2 trial paved the way for the Phase 3 ADAPT trial.*

By the time ARGS initiated its Phase 2 trial, tyrosine kinase inhibitors (TKIs) targeting VEGF receptors had become the standard-of-care for mRCC. In the era of targeted therapies, patients are stratified into risk groups based on the presence or absence of six readily available prognostic factors (Heng, 2009):

1) hemoglobin less than the lower limit of normal
2) serum corrected calcium greater that the upper limit of normal
3) Karnofsky performance status less than 80%
4) time from initial diagnosis to initiation of therapy less than one year
5) absolute neutrophil count greater than upper limit of normal
6) platelets greater than upper limit of normal

Patients with no adverse prognostic factors are considered good risk, those with one or two adverse factors are intermediate-risk and those with three or more are poor-risk. Patients with a favorable risk profile have a two-year survival rate of 75%. Intermediate-risk patients have a median OS of 27 months, and poor-risk patients have a median OS of around 8.8 months (Heng, 2009).

Clear cell carcinoma accounts for about 75% of all RCC. The remaining "non-clear" carcinomas are a heterogeneous assortment of cancers with different etiologies. While they may be amenable to immunotherapeutic treatment, they are generally less responsive to VEGF therapies. Thus, the Phase 2 trial (and the ongoing Phase 3 trial) exclude non-clear cell mRCC to avoid any confounding impact due to variable responsiveness to Sutent.

The AGS-003 Phase 2 trial tested Sutent + AGS-003 in 11 (52%) intermediate-risk and 10 (48%) poor-risk patients with newly diagnosed, clear cell metastatic renal cell carcinoma.

*AGS-003 looks promising with 11 intermediate-risk patients exhibiting an OS of 57.1 months in Ph2 vs historical 26-27-month OS.*

The 11 intermediate-risk patients had a median OS of 57.1 months, which compares favorably to the OS observed in intermediate-risk patients treated in a Phase 3 trial comparing Sutent and Votrient, where the median OS was 26 - 27 months (Motzer, 2014). The response was also broad. While only about 30% of intermediate-risk patients survived ≥40 months when treated with Sutent, Nexavar, or Avastin plus IFN-α (Heng, 2009), 7 out of the 11 (64%) intermediate-risk patients treated with AGS-003 survived ≥40 months.

*3/5 poor risk patients receiving at least 5 doses AGS-003 lived 30+ months.*

However, AGS-003 did not demonstrate an effect on OS in the poor-risk patients (median OS = 9.1 months). Five of 10 poor-risk patients were discontinued due to progressive disease before receiving five doses of AGS-003. Given that developing a successful immune response takes time, these patients likely never had an opportunity to develop a response. An increase in the number of memory T-cells per milliliter of blood, correlates with improved OS, consistent with the theory that generating new tumor specific T-cells plays an important role in the effectiveness of AGS-003. Notably, 3/5 poor-risk patients who did receive at least 5 doses AGS-003 survived ≥30 months.

**Phase 3 ADAPT Trial of AGS-003 + Sutent vs Sutent**

*The ADAPT trial aims to enroll 75% intermediate-risk and 25% poor-risk patients.*

The Phase 3 ADAPT trial also targets newly diagnosed intermediate and poor-risk mRCC patients. In contrast to the Phase 2 trial, the ADAPT trial has more stringent exclusion criteria and aims to enroll 75% intermediate-risk patients and only 25% poor-risk. Patients with 5 or 6 risk factors are excluded and only patients expected to survive at least 6 months are included. Patients are also allowed to switch from Sutent to another therapy if they fail to respond or are unable to tolerate Sutent. Additionally, AGS-003 can be dosed through progression.

One reason ARGS selected Sutent as the companion therapeutic is that Sutent suppresses $T_{REG}$ numbers and function. In one study with mRCC, Sutent reduced the number of circulating $T_{REG}$, and the level of reduction correlated with OS (Adotevi, 2010). Addtionally, the Sutent + AGS-003 combination may work synergistically, as AGS-003 generates a new population of freshly activated effector T-cells in the peripheral lymph nodes while Sutent prevents these activated effector T-cells from being suppressed by $T_{REG}$ in the tumor. Some studies suggest that Votrient and Avastin also inhibit $T_{REG}$ development and function. Thus, even if a substantial minority of patients in the

ADAPT trial are treated with an alternative standard of care, we do not expect this to dramatically impact the final outcome.

*The SPA with the FDA sets a HR of 0.708, which the Phase 2 data suggests should be achievable.*

The Special Protocol Assessment (SPA) that ARGS has with the FDA specifies a Hazard Ratio of 0.708 in OS will meet the FDA's threshold for approval. However, ARGS notes that many key opinion leaders believe a 4-month benefit would be clinically meaningful and significant. Given that the Phase 1 trial demonstrated an extension in OS to 18 months (from a historical 4 to 10 months) and the Phase 2 demonstrated an extension to 57 months (from a historical 27 months), we are optimistic that AGS-003 can show an OS of 22 months and a 6-month difference over the Sutent alone arm.

**AGS-003 Market Assumptions**

According to the Surveillance, Epidemiology, and End Results Program (SEER), 64,000 Americans are newly diagnosed with kidney cancer each year. Renal cell carcinoma (RCC) accounts for 90% of all kidney cancer and the most common form of RCC is "clear cell", which accounts for roughly 75% of all renal cancer. Papillary, chromophobe, collecting duct, medullary and other minor forms account for the remainder. These cancers are generally lumped together as "non-clear cell" though they may be quite heterogeneous in disease characteristics and progression (Rini, 2009).

For newly diagnosed localized tumors, stage I through stage III, the first-line therapy consists of partial or full nephrectomy. Surgical resection has a high success rate, with 80-90% 5-year overall survival (Roos, 2014). Unfortunately, as much as 30% of the RCC population presents as stage IV metastatic disease (Weiker and Ljungberg, 2010), and we estimate ~60% have a nephrectomy (Heng, 2014). See Exhibit 1.

| Patients With Primary Metastatic Clear Cell Renal Carcinoma in the US | |
|---|---|
| Number of New Kidney Cancer Patients US, 2015 | 62649 |
| % of Kidney Cancer That Is Renal Cell Carcinoma (RCC) | 90% |
| % of RCC Patients That Have Clear Cell Histology | 75% |
| % of Patients That First Present with Metastatic Disease | 30% |
| % of Patients with Intermediate Risk mRCC | 55% |
| % of mRCC that Undergo Nephrectomy | 60% |
| Addressable Population | 4187 |

*Sources: Company reports and MLV & Co. estimates.*

*Exhibit 1*

We estimate AGS-003 can show a HR of 0.708 at its third interim analysis at 75% events, which we predict will occur in 2H16, and that FDA will grant regulatory approval in 2H17. Given the promising Phase 2 data, we assign a cumulative 55% probability for AGS-003 to reach the US market (61% Phase 3 success, 95% regulatory success, 95% market success). We also assume AGS-003 will reach peak 25% penetration in 2022 with a 25% annual drop-out rate, and generate $400M in peak 2029 sales (See Appendix Table 3). For Europe and Japan, for which the regulatory pathway is less clear, we assume a lower 35% cumulative probability of success (65% Phase 2, 60% Phase 3, 95% regulatory, 95% market). We also assume lower 20% peak penetration in Europe. Together, we expect Europe and Japan to generate peak $350M revenue in 2029, representing $5 valuation to our SOTP analysis.

*We estimate AGS-003 US approval in 2017 and 25% peak penetration to generate $400M peak sales.*

**Upside from Metachronous mRCC Market**

Approximately 30% of patients who undergo a nephrectomy for stage 1-3 RCC do eventually relapse with metastatic disease, referred to as metachronous metastases (Stewart, 2014). If RNA could be harvested from the metastatic lesions this would roughly double the addressable population. ARGS is collaborating on a trial to optimize the use of needle biopsies for extracting RNA for priming dendritic cells in the Arcelis Platform. Given that RNA extraction from needle biopsies of renal cancer samples yielded high quality material in preclinical studies and that RNA has been extracted from needle biopsies of other tumor types (Kurban, 2012; Sasaki, 2014), we think it is highly probable that needle biopsies will provide acceptable RNA for use in the Arcelis Platform. It is not clear whether a separate Phase 3 trial would be required for the metachronous patient population. We currently do not include estimates for metachronous metastases in our model.

*Metachronous mRCC patients could roughly double the addressable population for AGS-003.*

**Additional Indications for AGS-003 Represent Upside to Our Estimates**

We expect ARGS to initiate a Phase 2 trial in non-clear cell RCC in 2015. If this includes metachronous as well as synchronous metastatic patients, it could represent 4,000 - 5,000 patients in the US. We also anticipate a second Phase 2 trial in a large indication such as breast cancer or non-small cell lung cancer, both of which have ~200,000 new cases annually. Additionally, one of these clinical trials will likely combine AGS-003 with a checkpoint inhibitor such as blockers of PD-1 or the PD-

*We expect ARGS to initiate trials in other indications in 2015*

1Ligands. Because AGS-003 appears to generate new populations of memory and effector T-cells, and PD-1 blockers prevent those T-cells from being directly inhibited by the cancer cells, we think such a combination could be highly synergistic, potentially leading to faster responses with higher objective response rates.

## NEXT PRODUCT CANDIDATE AGS-004 FOR HIV ERADICATION AND ELIMINATION

### AGS-004 Phase 2 Results Indicate Immune Effect

*AGS-004 for HIV also uses the Arcelis Platform and is funded from non-dilutive sources.*

AGS-004 also uses the Arcelis Platform for its foundation. AGS-004 uses HIV RNA derived from the blood of patients prior to initiating anti-retroviral therapy (ART). To date ARGS has not demonstrated the capacity to eradicate HIV in its clinical trials. We therefore do not attribute any valuation to this program in our model. However, AGS-004 has shown interesting signs of immunological activity and no significant adverse events attributable to therapy in any treated patient. We view these results as validation of the Arcelis Platform. AGS-004 is funded entirely by non-dilutive grants.

*Phase 2b AGS-004 ART treatment interruption failed due to lack of patient compliance with trial protocol which went against medical consensus.*

The Phase 2b trial failed to meet the primary endpoint of a 1.1 log reduction in median viral load in treated vs placebo patients after 12 weeks of interrupting ART. While ART interruption was permissible at the time the trial was initiated, medical consensus changed to recommend against ART interruption during the trial. Thus, it is not surprising that the blood of many trial patients indicated they did not fully stop taking ART during the 12-week interruption period, obscuring the results. Furthermore, a significant proportion of patients did not have reliable pre-trial data points. Overall, we are not surprised the Phase 2 trial did not meet its primary endpoint, and ARGS is designing future trials without treatment interruption as a component of the primary endpoint.

*AGS-004 treatment generated memory T-cells and impacted viral reservoir.*

Interestingly, the Phase 2b data did indicate memory T-cells were generated and impacting the viral reservoir. Fifty-four patients received four doses of AGS-004 or placebo every four weeks while on ART, then initiated 12 weeks of ART interruption during which time 3 additional doses of AGS-004 were administered. Thirty-six participants completed the study, 23 of whom received AGS-004. Approximately 70% had positive antiviral memory T-cell responses vs 0% placebo patients.

Compellingly, patients with antiviral memory T-cell responses had significantly fewer CD4+ T-cells with integrated HIV DNA than the non-responders, indicating AGS-004 resulted in fewer CD4+ T-cells infected with HIV.

This data is consistent with 2011 Phase 2 results. The enrollment criteria for the 2011 Phase 2 included:

1) Patient had received ART for at least 3 months.
2) HIV-1 Viral load <50 copies/mL and CD4+ T cell count ≥450 cell/$mm^3$ for at least 90 days
3) Availability of ≥ 1.2 mL of pre-ART frozen plasma
4) Pre-ART nadir CD4+ T cell count ≥200 cells/$mm^3$

*Second Phase 2 AGS-004 showed effect on immune control of HIV.*

Eight of 24 subjects (33%) met the primary endpoint, which was the ability of AGS-004 to promote immune control of HIV-1, as measured by the proportion of subjects with HIV-1 RNA levels of <1000 copies/mL on at least three time points after the initiation of a 12-week ART interruption. 21/24 patients remained off of ART for the full 12 weeks (meaning their viral load did not exceed 10,000 copies per ml and/or their CD4 T-cell counts did not drop below 350 cells/$mm^3$) and four remained off of ART for 47, 57, 68, and 108 weeks. The median time off of ART was 18.1 weeks and 66% of the patients had no viral rebound at two weeks post-interruption. For comparison, in an ART interruption study with a cohort of Swiss patients, only 14.3% (2 out of 14) had no viral rebound two weeks after interruption (Fischer, 2003).

Taken together, the Phase 2 trials are consistent with the hypothesis that AGS-004 provokes an anti-viral response and consequently reduces the viral load.

**AGS-004 Combination Trials in HIV**

*ARGS will advance AGS-004 program into combination trials with HDAC and immune checkpoint inhibitors*

The challenge for ARGS is to move beyond viral depletion to achieve viral elimination and eradication. Argos plans to initiate trials to push the system to the next level. The first strategy is to use additional modulators of immune inhibition to help provoke the immune system into a response. Studies have correlated the size of the HIV reservoir correlates with the frequency of PD-1 expressing T-cells in the peripheral blood (Chomont, 2009). Thus, blockers of PD-1 or the PD-1 ligands would be reasonable combinations with AGS-004. The second strategy is to activate latent HIV so that it becomes more visible to the immune system. Histone deacetylase (HDAC) inhibitors activate latent

HIV in patients on ART (Elliot, 2014). We also anticipate that ARGS will launch a Phase 2 trial combining AGS-004 with an HDAC inhibitor such as Zolinza by mid-2015. We expect these trials to use a primary endpoint such as undetectable virus for one year rather than the treatment interruption endpoint that was used in earlier trials.

**HIV Market**

Currently the Center for Disease Control (CDC) estimates that there are 50,000 new HIV cases each year in the United States. However, since HIV is currently incurable, but lifespan has been significantly extended by the use of ART, the US HIV prevalence is 1.2 million patients.

Numerous vaccines and therapies have failed to prevent or cure HIV. However, there is a population of people who naturally generate potent CD8+ T-cell responses that control HIV-1 by selectively killing infected cells. As this is the type of response that the AGS-004 provokes, there is some reason for optimism.

AGS-004 is particularly well-suited to overcome HIV's high rate of mutation since it uses a broad sampling of the antigen repertoire present in the clone that infected the patient. If AGS-004 demonstrates promise in the upcoming Phase 2 trials, we expect ARGS to out-license the program for further development. However, pending clinical and commercial validation, we currently ascribe no valuation for AGS-004.

**AGS-003 MANUFACTURING LOGISTICS AND ECONOMICS**

*ARGS has developed an automated system designed to make personalized medicine more affordable.*

ARGS intends to manufacture AGS-003 in-house using proprietary equipment and processes. Assuming Phase 3 success for AGS-003 in mRCC, we believe investors will next focus on ARGS's commercial manufacturing process.

According to ARGS, a single production run will cost ~$20,000 (excluding equipment depreciation) and generate 15-20 doses of AGS-003 that can be frozen for at least five years. With automation and production learning and efficiencies, we expect ARGS can achieve $15,000 per run. We note a significant portion (~2/3 to 3/4) of cost of goods sold will be in consumables (proprietary disposables and reagents).

We estimate these 15-20 doses are enough for 3-4 years' worth of therapy for mRCC. Not every patient will receive all doses. We assume ARGS can charge $10,000 - $15,000 per dose.

Assuming the average patient receives 14 doses, over the course of three years, at $12,000 per dose, the cash production costs may represent about 12% of the cost of a course of treatment.

In the case of mRCC the source of tumor sample will be from a nephrectomy or partial nephrectomy, in which the kidney is removed from the patient. Once the surgeon transfers the specimen into a vial with RNA stabilization solution, the tumor sample is stable at room temperature for weeks. We estimate ~1% failure rate due to harvest of necrotic tissue or inappropriate handling. Though we believe use of needle biopsies will require multiple samples be collected, it should not materially affect quality or operating cost.

Once the tumor sample reaches ARGS's centralized facility, it is manually homogenized and loaded into a machine that extracts the RNA, converts it to DNA, amplifies it, and reverse transcribes it back to RNA. This process takes ~14 hours and is conducted within a closed disposable that keeps the sample sterile and avoids cross-contamination. The RNA yield generally provides enough material to last years and can be frozen until needed. The RNA product is tested for purity and sterility.

Since the RNA processing procedure takes ~2 days, the number of machines that can run samples could become limiting. ARGS estimates twenty-eight machines should be able generate sufficient product for ~2500 patients annually.

Following nephrectomy, patients require 6-8 weeks recovery, during which they undergo a leukapheresis to extract white blood cells from the plasma over the course of about four hours. This yields approximately one billion monocytes from which the dendritic cells will be derived. These cells are shipped fresh to ARGS's central processing facility, preferably overnight.

Once the cells arrive at ARGS's centralized facility, the plasma is removed and stored for later processing while the monocytes are further enriched through elutriation. The purified cells mature for five days in the presence of GM-CSF and IL-4, in proprietary culture conditions, to generate activated dendritic cells. The dendritic cells are then loaded with the RNA extracted from the patient's tumor as well as with RNA encoding the costimulatory molecule CD40-ligand. After the RNA-loaded dendritic cells recover in culture for another day, they are mixed in the patients' previously removed serum and frozen in vials until needed. A sample vial of the final product is

thawed and tested to confirm the cells are viable, express the desired immune-markers, are sterile and produce the pro-inflammatory cytokine IL-12.

ARGS intends to store half of the finished product in liquid nitrogen on site and store half of the vials with a third party as part of a risk-mitigation strategy. The whole process, from the time the tumor is harvested until the time the product is certified to ship, takes 5-6 weeks. In indications that do not require surgical recovery, the process could be reduced to 2 to 3 weeks.

ARGS ships the frozen vials to the clinic or pharmacy in a standard liquid nitrogen flask when needed. The drug product is stable for two weeks in the cryoshipper. ARGS believes no special handling is required to thaw and administer the vaccine. The patient receives eight immunizations in the first year and four booster shots each subsequent year. We note that AGS-003 dosing frequency in the first year for mRCC is timed to coincide with breaks in the Sutent dosing schedule, to minimize exposure of the dendritic cells to the toxic effects of Sutent. Each vaccine contains ~10 million mature dendritic cells injected subcutaneously at three sites, in about 0.2mL per site.

ARGS has invested considerable effort in optimizing each step of the production process. Most procedures are conducted by robotics within sterile disposables, which should minimize risk of contamination and sample mix up, as well as facility and personnel requirements. While the planning process for AGS-003 is early, ARGS intends to run 2-3 shifts 24/7 for 48 weeks out of the year. Peak manufacturing headcount is expected to total 140. Including QC, QA, and other commercialization support, peak headcount will total ~300.

Machinery and disposables have been custom-designed and are patent-protected. ARGS has contracted with privately-held Invetech for machinery and Saint-Gobain's (Depository Receipt: CODYY – Not Rated) Performance Plastics division for proprietary consumables. We estimate that total capital investment in machinery and support equipment for mRCC will be ~$35 million. The equipment is expected to have an average useful life of 15 years and a depreciable life of seven years. Additionally, on December 29, 2014, ARGS exercised an option to purchase a new, built to suit 11-acre, 97,500 square foot manufacturing facility in Durham, NC. The option purchase price for the structure was $7.62 million, and ARGS estimates

the buildout and furnishing will require an additional $34-$40 million in capital. This does not include the aforementioned $35 million in equipment cost. Argos is in the process of securing financing for the building, which is expected to be a combination of a long-term sale leaseback and some shorter-term debt.

ARGS believes its AGS-003 process is scalable to meet patient demand. Initially, ARGS will have the capacity to process samples for 2500 mRCC patients annually, with the ability to build out to 10,000 patients per year. Furthermore, we note that mRCC is just one indication that ARGS will be targeting. We believe the AGS-003 process is readily adaptable for other solid tumors.

**AGS-003 Commercialization Assumptions**

In our financial model, we assume that ARGS will retain exclusive rights to AGS-003 for mRCC in the United States and Western Europe (2018 and 2019 launch dates, respectively). We assume ARGS will outlicense AGS-003 for mRCC in Japan (2020 launch date), with an assumed royalty rate of 8%. In the US we assume a selling price of $12,000 per dose (with an annual inflation escalator) and an average cash cost of $20,000 for 12 doses (which we expect to decline over time with production efficiencies). We estimate peak sales of $411 million, $285 million, and $67 million, for the US, EU, and Japan, respectively.

We expect ARGS to ramp up its US and EU sales force shortly ahead of the regional launches, with 64 salespeople to be hired in the US and 32 in the EU at standard industry compensation rates.

## COMPETITIVE LANDSCAPE

**Other Immuno-Therapies for mRCC**

*A Phase 3 trial of Opdivo (PD-1 blocker) paired with Yervoy (CTLA4 blocker) in front-line mRCC represents potential competition for AGS-003.*

Bristol-Myers Squibb (BMS, Not Rated) and Ono Pharmaceutical Company (OPHLY, Not Rated) are currently sponsoring a Phase 3 trial for Opdivo, a PD-1 blocker, combined with Yervoy, a CTLA-4 blocker, relative to Sutent in front-line mRCC. The primary completion date for the trial is listed as January 2018. A Phase 2 Opdivo trial in pre-treated mRCC showed a median OS of 18 - 25 months vs historical OS rates in the 12 - 16 month range, suggestive of activity. However, it remains to be seen

whether risk-benefit profile of the combination is similarly attractive. If the Opdivo + Yervoy combination therapy receives regulatory approval, it would compete with AGS-003 + Sutent for first-line mRCC.

*Immatics Biotechnologies expects readout from a Phase 3 trial of their peptide vaccine IMA901 in mRCC by mid-2015. We see this as a moderate risk factor for ARGS.*

IMA901 (Immatics Biotechnologies, Private) is another vaccine based therapy for mRCC currently in a 330-patient Phase 3 trial (IMPRINT) with an anticipated completion date of mid-2015. The Phase 3 IMPRINT trial is very similar to the ADAPT trial in that it measures the OS benefit to patients with metastatic clear cell RCC treated with IMA901 in combination with Sutent versus those treated with Sutent alone. It differs from the ADAPT trial in that it is recruiting good and intermediate-risk patients, but not poor-risk patients. Because good risk patients treated with Sutent have such a long OS, median OS not reached at 3 years (Motzer, 2009), it requires a long time and/or a very large effect for IMA901 to show a significant benefit.

Unlike AGS-003, IMA901 is not a personalized, dendritic-cell-based vaccine. It consists of a cocktail of nine peptides identified as being present at a high frequency in a panel of 42 RCC tumors. These peptides are not mutated in the target cancer, and thus the vaccine essentially attempts to elicit an autoimmune response. The vaccine also contains recombinant GMCSF as an adjuvant. The peptides that were selected are presented in the context of the HLA-A*02 major histocompatibility complex molecule, which is present in about 30% of the US population (Oh, 2005). If the IMPRINT trial meets its primary objective, IMA901 would at most compete with AGS-003 for 30% of the intermediate-risk population.

The Phase 2 trial of IMA901 did show signs of efficacy in second-line mRCC, though there were clear indications that it did not perform equivalently in all patient populations, and it's not clear to us how to extrapolate these results to the frontline setting. The Phase 2 trial was conducted with or without cyclophosphamide to deplete the $T_{REG}$ population. The OS in the

**IMA901 Phase 2 Data in mRCC Patients Previously Treated With Systemic Therapies (anti-VEGF or Cytokine Therapy). Median Overall Survival at 33 Months.**

| | Failed Prior anti-VEGF or Cytokine Therapy | | Cytokine Failure Group | | Historical Data in Cytokine Failure Patients | |
|---|---|---|---|---|---|---|
| | CYP | no CYP | CYP | no CYP | Placebo | Sorafenib |
| n | 31 | 33 | 20 | 20 | 452 | 451 |
| OS (months) | 23.5 | 14.8 | Not Reached | 15.8 | 15.2 | 17.8 |

CYP = Cyclophosphamide

*Sources: Company reports and MLV & Co. estimates. ; Walter, 2012*

*Exhibit 2*

Phase 2 study was 23.5 months for the 31 patients who received cyclophosphamide and 14.8 months for the 33 who did not (Exhibit 2), which is a positive result. When the data from patients who had failed previous anti-VEGF therapies was excluded, the median OS had not yet been reached at 33 months. While this data looks good relative to historical data (15 to 18 months OS) on patients who failed cytokine therapy, the difference is largely driven by two patients who were strong responders, as assessed by immunological parameters. This type of response is reminiscent of the small population of patients who have long term responses to IL-2 therapy. We think IMA901 would need to achieve broad responses to achieve significance and garner FDA approval.

Immunicum (IMMU, Not Rated) is developing an allogeneic dendritic cell therapy for mRCC with plans to initiate a Phase 2 trial in 2015. With only 11 evaluable patients in the Phase 1/2 trial, it is difficult to evaluate efficacy, and we do not currently view this as a significant threat to AGS-003. However, if allogeneic dendritic cell therapies do demonstrate clinical efficacy, they would be less expensive to produce than autologous dendritic cells.

**Dendritic Cell Vaccines in Other Indications**

As the first dendritic-cell-based anticancer immunotherapy to be approved by the FDA, Dendreon's sipuleucel-T (Provenge) for prostate cancer both paved the way and left a bumpy path for AGS-003. Sipuleucel-T demonstrated dendritic-cell-based vaccines could increase the overall survival (OS) in cancer

patients. Due to the high production cost and logistics of producing Provenge, Dendreon struggled to make a profit, eventually filing for Chapter 11 bankruptcy. Even if Dendreon is successfully resurrected by Valeant, we do not view Provenge as a direct competitor to the Arcelis Platform.

*Northwest Biotherapeutics has a very similar platform to ARGS which is progressing in other indications including glioblastoma, prostate, and ovarian cancer.*

Northwest Biotherapeutics (NWBO, Not Rated) has developed a dendritic cell vaccine, called DCVax, which is very similar to the Arcelis Platform. They also harvest patient monocytes and culture them to generate mature dendritic cells. Currently enrolling patients in a Phase 3 trial for gliobastoma, NWBO uses tumor lysates or peptides to load their dendritic cells, in contrast to the RNA used by ARGS. Though preclinical studies suggest RNA-loaded dendritic cells are better at presenting antigen than dendritic cells loaded with lysates (Fry, 2009; Pan, 2010), we are not aware of any data indicating that one method is superior to the other in a clinical setting. At the moment, NWBO is focused on glioblastoma, prostate, and ovarian cancer, whereas ARGS is concentrating on renal, breast, and lung cancers. Therefore, it may be some time before the two companies compete directly on a given indication.

Immunocellular Therapeutics (IMUC, Not Rated) is also developing autologous dendritic cell vaccines. Lead program in glioblastoma plans to initiate a Phase 3 trial in 2015. A Phase 2 trial in ovarian cancer is also planned. Unlike ARGS and NWBO that load dendritic cells with patient-specific antigens, IMUC uses 4 tumor associated peptides from proteins highly expressed on cancer cells. Similar to Provenge and IMA901, this strategy essentially seeks to elicit an autoimmune response against normal proteins that are expressed at higher levels in tumor cells. We prefer strategies that target mutated proteins.

Several other companies have early stage programs using allogeneic dendritic cells. DC Prime (private) is conducting a Phase 1 trial for the treatment of acute myelogenous leukemia and Immunicum has a Phase 1 program in liver cancer.

**INTELLECTUAL PROPERTY**

ARGS holds a number of patents and patent applications pertaining to the methods of manufacturing as well as compositions of matter and products for the Arcelis Platform. These include U.S. Patent No. 8,822,223, which describes the methods used for preparing and maturing the dendritic cells used in AGS-003 and AGS-004, and U.S. Patent 8,211,701 which pertains to the use of the automated RNA processing apparatus.

These patents expire in 2025 and 2027 respectively. ARGS also believes they have know-how and trade secrets that would be essential to replicating the Arcelis Platform.

**COMPANY DESCRIPTION**

Argos Therapeutics is a Durham, NC based, clinical-stage biotechnology company focused on the development of personalized immunotherapies for treating cancer and infectious diseases. Argos's lead candidates are based on the proprietary Arcelis process, which uses patient derived dendritic cells to galvanize the immune system into a disease specific response. Argos has a pivotal study currently under way in newly diagnosed metastatic renal cell carcinoma. In addition, they have a fully funded program addressing HIV elimination and eradication in adult and pediatric patients.

**COMPANY LEADERSHIP**

**Jeffrey D. Abbey, M.B.A., J.D. President and Chief Executive Officer.** Mr. Abbey joined Argos in 2002 and served various roles, including Vice President of Business Development and Chief Business Officer, before assuming the position of CEO in 2010. Prior to joining Argos, Mr. Abbey served as Vice President of Business Development and Finance at Internet Appliance Network, an information technology company. Mr. Abbey was also a partner at a corporate Law Firm, Eileberg and Krause, LLP from 1994 to 1999.

**Frederick M. Miesowicz, Ph.D. Chief Operating Officer.** Dr. Miesowicz joined Argos in 2003 as Vice President of Manufacturing. In 2005 he took on the added responsibilities of COO. Dr. Miesowicz has held senior level positions in the bio-pharmaceutical industry since 1995. Prior to joining Argos he served as Vice President of U.S. Operations for Gamida-Cell Ltd., a stem cell company; Senior Vice President and General Manager at Hybridon Specialty Products, a biotechnology company; and Vice President and General Manager at Cellcor, a subsidiary of the biopharmaceutical company Cytogen Corporation.

**Charles A. Nicolette, Ph.D. Chief Scientific Officer.** Dr. Nicolette has served as CSO since December 2007 and prior to that as Vice President of Research and Development. Before joining Argos, Dr. Nicolette held the position of Director of Antigen Discovery as well as other positions at Genzyme Molecular Oncology, Inc.

**Lori R. Harrelson C.P.A., Vice President of Finance.** Before becoming VP of Finance in 2009, Ms. Harrelson served as the Director of Finance and Accounting and as the Director of Accounting and Financial Reporting at Argos. Ms. Harrelson has also served as Finance Manager at the diagnostic company LipoScience, Inc.

**Douglas C. Plessinger, RPh, Vice President of Clinical and Medical Affairs.** Mr. Plessinger joined Argos in 2011, having consulted for Argos since 2007. Previously Mr. Plessinger served as Executive Vice President and Managing Director at Axcelo MSL Solutions, LLC, an oncology consulting company. Mr. Plessinger was also a founding partner and Managing Director of its predecessor company, venn5 BioConsulting. Prior to this, he served as Senior Vice President, Account Services at The Navicor Group, LLC, a healthcare advertising agency. He also gained experience as an Oncology Medical Science Liaison at Millennium Pharmaceuticals, Inc., and in various Medical Affairs and Product Development roles at Bristol-Myers Squibb Oncology.

**Hubert Birner, Ph.D., Chairman of the Board.** Dr. Birner originally joined the board in 2001 and assumed the chairmanship in 2005. Dr. Birner is a Managing Partner at TVM Capital, a venture capital firm and affiliate of Argos. Dr. Birner served as head of European business development and director of marketing for Germany at Zeneca Agrochemicals, a biopharmaceutical company. Dr. Birner also served as a management consultant in McKinsey & Company´s European healthcare and pharmaceutical practice. Dr. Birner currently serves on the board of directors of Proteon Therapeutics, Inc. and SpePharm Holdings BV.

## VALUATION

***Valuation Approach: Probability-Weighted Valuation of Pipeline Assets and Partnerships (Appendix Tables)***

We derive a value of $13 per ARGS common share based on a sum-of-the-parts analysis, whereby we value each drug candidate based on a discounted earnings forecast. We project worldwide sales as well as royalty revenue and milestone revenue (where applicable) and cost of goods sold, R&D expense, and SG&A through 2029.

This valuation methodology takes into account the expected after-tax profits through 2029. Our forecast includes AGS-003 for mRCC and no other solid tumor indications.

For Phase 3 candidate AGS-003 (for mRCC) we assign a probability of 55% that the drug will make it to market in the United States. For the EU and Japan, we are assigning each a 35% probability of success.

We forecast after-tax profit streams through 2029 which are then adjusted (*i.e., "*haircutted") for the probability of reaching the market, as well as a 2029 terminal value (which assumes 0% terminal growth rate). We discount these probability-adjusted profit streams back at a 10% rate, which we use as a baseline level of riskiness.

For modeling purposes, we allocate 100% of direct and indirect R&D, manufacturing development R&D, and SG&A expense to the U.S. For the U.S. and EU regions we also allocate the incremental sales expense to be incurred by each region.

Our $13 per share valuation breaks down as follows:

- AGS-003 for mRCC – US - $8
- AGS-003 for mRCC – EU - $5
- AGS-003 for mRCC – Japan - $0

In our valuation, we do not include cash on hand since we expect ARGS to burn cash to develop its pipeline. We estimate that cash and cash equivalents on hand should fund operations through mid-2015. We deduct from the valuation ~$67 million in funded (and to be funded) debt. We anticipate that ARGS will raise additional debt and equity capital in 2015 and beyond.

**INVESTMENT RISKS**

Risks to our outlook include clinical and regulatory delays, commercialization risk, financing risk, and intellectual property risk.

**Clinical and regulatory risk.** ARGS is a development stage company that has yet to attain regulatory approval for any drug candidate, and it is possible it may never do so. Currently, its most advanced candidate, AGS-003, is in a Phase 3 trial for metastatic renal cell carcinoma. Based on the SPA agreement they have with the FDA, a successful Phase 3 trial should enable ARGS to file for FDA approval. However, AGS-003 could fail to show sufficient risk/benefit profiles to support regulatory

approval. Additional information and/or additional trials could be required by regulators to address any safety or efficacy concerns. If this were to occur, this could significantly delay revenue generation going forward, and could materially impact our forecasts.

**Commercial risk.** ARGS is taking on debt to develop their infrastructure and manufacturing capabilities. They also need to develop a sales force for AGS-003. ARGS could be unable to generate the revenues we forecast. Lack of uptake by physicians, patients or payers due to more efficacious and/or easier to adhere to treatment options will also affect our revenue projections and thus, our valuation.

**Financing risk.** Currently, ARGS is cash-flow negative, and therefore is likely to require additional funding. We estimate ARGS will need to raise cash before first drug approval. Subsequent equity raises would dilute current shareholders and lower expected returns for investors. The incurrence of additional debt could increase the risk of financial distress. Separately, we believe ARGS will need to amend its $25 million Venture Loan and Security Agreement (dated September 30, 2014) before the Company can incur additional debt and mortgage property. Failure to do so in a timely manner may disrupt ARGS' plan to finance its manufacturing facility.

**Developmental failure risk:** Argos is expected to finance the construction of its manufacturing facility this year, incurring the equivalent of $40-$45 million in debt. In the event that the Phase 3 data (expected in 2Q-3Q 2016) fails to demonstrate an effect and ARGS does not commercialize the Arcelis Platform, this (and other funded debt) will be ahead of equity holders in the event of a liquidation.

**Intellectual property risk.** Argos's issued patents may be invalidated or expire, allowing additional competitors to enter their markets.

**APPENDIX TABLE 1**

**Argos Therapeutics Inc. (ARGS) Probability Weighted Sum of the Parts Discounted Earnings Valuation ($MM)**

| Drug | Peak Sales ($ MM) | Stage | (Estimated) Launch | Probability of Reaching Market | ARGS Share of Revenue | Probability Adjusted NPV | Per Share Value |
|---|---|---|---|---|---|---|---|
| AGS-003 for mRCC - US | $411 | 3 | 2017 | 55% | 100% | $423 | $8 |
| AGS-003 for mRCC - EU | $285 | 2 | 2018 | 35% | 100% | $253 | $5 |
| AGS-003 for mRCC - Japan | $67 | 3 | 2019 | 35% | 8% | $8 | $0 |
| AGS-004 for HIV | -- | | -- | -- | -- | -- | -- |

| Cash | |
|---|---|
| Cash (12/31/14) | $55 |

| | |
|---|---|
| Total firm value including cash | $740 |

| Debt | Face ($MM) |
|---|---|
| L+875 Venture Loan Tranche 1 due 9/30/18 | 13 |
| 3% Medinet Loan due 12/31/18 | 0 |
| L+875 Venture Loan Tranche 2 due 12/31/18 | 13 |
| Manufacturing Facility Financing (TBA) | 42 |
| Total Debt | 67 |

| | |
|---|---|
| Equity value excluding cash | $617 |
| Shares Outstanding YE 2029 (MM) | 48.4 |
| Equity value per share | $13 |

| | |
|---|---|
| Discount Rate | 10.0% |
| Time of Valuation | 2/24/15 |

*Note: Numbers may not add due to rounding*
*Sources: Company reports and MLV & Co. estimates.*

## APPENDIX TABLE 2

**Argos Therapeutics Inc. (ARGS) - AGS-003 (mRCC) United States Probability Adjusted Discounted Earnings Valuation ($MM)**

| | |
|---|---|
| Discount Rate | 10.0% |

| Probability of Success | Per Stage |
|---|---|
| **Preclinical** | 100% |
| **Phase I** | 100% |
| **Phase II** | 100% |
| **Phase III** | 61% |
| **FDA** | 95% |
| **Market** | 95% |
| Cumulative | 55% |

| | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue Forecast ($MM)** | **0.0** | **0.0** | **0.2** | **9.6** | **46.1** | **107.0** | **176.6** | **219.8** | **255.0** | **286.1** | **314.2** | **340.1** | **364.5** | **388.0** | **411.0** |
| Milestone Forecast | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

| Stage | Phase 3 | FDA | Market | Market | Market | Market | Market | Market | Market | Market | Market | Market | Market | Market | Market |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Cash COGS | 0.0 | 0.0 | 0.0 | 1.3 | 5.7 | 12.3 | 18.7 | 21.5 | 23.0 | 25.0 | 26.7 | 28.0 | 29.1 | 30.1 | 31.0 |
| 100% equipment depreciation COGS | 0.9 | 5.0 | 5.0 | 5.0 | 5.0 | 5.0 | 5.0 | 8.4 | 4.3 | 4.3 | 4.3 | 4.3 | 4.3 | 4.3 | 0.0 |
| 100% AGS-003 direct R&D | 20.0 | 20.0 | 10.0 | 5.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| 100% AGS-003 manufacturing development R&D | 14.0 | 14.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| 100% indirect R&D expense | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 | 18.0 |
| 100% SG&A excluding US sales expense | 13.1 | 15.0 | 15.6 | 16.0 | 16.4 | 16.8 | 17.2 | 17.7 | 18.1 | 18.6 | 19.1 | 19.6 | 20.1 | 20.6 | 21.1 |
| AGS-003 US sales expense | 0.0 | 8.0 | 16.5 | 17.0 | 17.5 | 18.0 | 18.5 | 19.1 | 19.7 | 20.3 | 20.9 | 21.5 | 22.1 | 22.8 | 23.5 |
| **Total Costs** | **66.0** | **80.0** | **65.1** | **62.3** | **62.6** | **70.1** | **77.5** | **84.7** | **83.0** | **86.2** | **88.9** | **91.4** | **93.7** | **95.8** | **93.6** |

| Stage | Phase 3 | FDA | Market | Market | Market | Market | Market | Market | Market | Market | Market | Market | Market | Market | Market | Terminal value at 2030 | Assumed growth rate |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Probability | 55% | 55% | 55% | 55% | 55% | 55% | 55% | 55% | 55% | 55% | 55% | 55% | 55% | 55% | 55% | | |
| Prob. Adjusted Revenue | 0.0 | 0.0 | 0.1 | 5.3 | 25.4 | 58.9 | 97.2 | 121.0 | 140.4 | 157.5 | 173.0 | 187.2 | 200.7 | 213.6 | 226.3 | | |
| Prob. Adjusted Total Cost | 36.3 | 44.0 | 35.8 | 34.3 | 34.5 | 38.6 | 42.7 | 46.6 | 45.7 | 47.4 | 48.9 | 50.3 | 51.6 | 52.8 | 51.5 | | 0% |
| Effective tax rate | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 35% | 35% | 35% | 35% | 35% | 35% | 35% | | |
| Prob. Adjusted Profits | (36.3) | (44.0) | (35.8) | (29.0) | (9.1) | 20.3 | 54.6 | 74.4 | 61.5 | 71.6 | 80.6 | 89.0 | 96.9 | 104.6 | 113.6 | 1,135.7 | |
| Shares (MM) | 24.9 | 34.9 | 45.4 | 45.4 | 45.4 | 48.4 | 48.4 | 48.4 | 48.4 | 48.4 | 48.4 | 48.4 | 48.4 | 48.4 | 48.4 | 48.4 | |
| Per Share | (1.46) | (1.26) | (0.79) | (0.64) | (0.20) | 0.42 | 1.13 | 1.54 | 1.27 | 1.48 | 1.66 | 1.84 | 2.00 | 2.16 | 2.35 | 23.46 | |
| **Line 1:** Present Value of Probability Adjusted Profits ($MM) | (33.5) | (36.9) | (27.3) | (20.1) | (5.7) | 11.6 | 28.4 | 35.2 | 26.5 | 28.0 | 28.7 | 28.8 | 28.5 | 27.9 | 27.6 | 275.8 | |
| **Line 2:** Present Value of Probability Adjusted Profits/Share ($MM) | (1.34) | (1.06) | (0.60) | (0.44) | (0.13) | 0.24 | 0.59 | 0.73 | 0.55 | 0.58 | 0.59 | 0.59 | 0.59 | 0.58 | 0.57 | 5.70 | |

| | |
|---|---|
| **Probability-Adjusted NPV- Line 1 ($MM)** | **$423.4** |
| **NPV of Prob. Adj. Profits per share - Line 2** | **$ 7.73** |
| **Time of Valuation** | 2/24/15 |

*Sources: Company reports and MLV & Co. estimates.*

## APPENDIX TABLE 3

| US Kidney Cancer | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Newly Diagnosed Kidney Cancer Patients | 62,649 | 63,589 | 64,543 | 65,511 | 66,493 | 67,491 | 68,503 | 69,531 | 70,574 | 71,632 | 72,707 | 73,797 | 74,904 | 76,028 | 77,168 |
| Clear Cell RCC | 42,288 | 42,922 | 43,566 | 44,220 | 44,883 | 45,556 | 46,240 | 46,933 | 47,637 | 48,352 | 49,077 | 49,813 | 50,560 | 51,319 | 52,089 |
| Clear Cell, Metastatic RCC | 12,686 | 12,877 | 13,070 | 13,266 | 13,465 | 13,667 | 13,872 | 14,080 | 14,291 | 14,506 | 14,723 | 14,944 | 15,168 | 15,396 | 15,627 |
| Intermediate-Risk, Clear Cell mRCC | 6,978 | 7,082 | 7,188 | 7,296 | 7,406 | 7,517 | 7,630 | 7,744 | 7,860 | 7,978 | 8,098 | 8,219 | 8,342 | 8,468 | 8,595 |
| Addressable Int-Risk, Clear Cell mRCC (Nephrectomy | 4,187 | 4,249 | 4,313 | 4,378 | 4,443 | 4,510 | 4,578 | 4,646 | 4,716 | 4,787 | 4,859 | 4,932 | 5,005 | 5,081 | 5,157 |
| | | | | | | | | | | | | | | | |
| AGS-003 Penetration in mRCC | | | 0.2% | 5% | 12% | 20% | 24% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% |
| AGS-003 mRCC New Patients | | | 9 | 219 | 533 | 902 | 1,099 | 1,162 | 1,179 | 1,197 | 1,215 | 1,233 | 1,251 | 1,270 | 1,289 |
| Doses in Year 1 | | | 1.5 | 4 | 6 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| Annual Drop-Out Rate | | | | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% |
| AGS-003 Booster Patients | | | | 6 | 169 | 527 | 1,072 | 1,628 | 2,092 | 2,453 | 2,737 | 2,964 | 3,148 | 3,299 | 3,427 |
| Doses in Year 2+ | | | | 2 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | | | | | | | | | | | | | | | |
| Price per Dose (Thousands) | | | $ 12 | $ 12 | $ 13 | $ 13 | $ 14 | $ 14 | $ 14 | $ 15 | $ 15 | $ 16 | $ 16 | $ 17 | $ 17 |
| US Newly Diagnosed Sales ($MM) | | | $ 0.2 | $ 9 | $ 41 | $ 83 | $ 119 | $ 129 | $ 135 | $ 141 | $ 148 | $ 154 | $ 161 | $ 169 | $ 176 |
| US Booster Sales ($MM) | | | $ - | $ 0 | $ 5 | $ 24 | $ 58 | $ 91 | $ 120 | $ 145 | $ 166 | $ 186 | $ 203 | $ 219 | $ 235 |
| US mRCC Sales ($MM) | | | $ 0.2 | $ 9.6 | $ 46.1 | $ 107.0 | $ 176.6 | $ 219.8 | $ 255.0 | $ 286.1 | $ 314.2 | $ 340.1 | $ 364.5 | $ 388.0 | $ 411.0 |

| EU 28 Kidney Cancer | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Newly Diagnosed Kidney Cancer Patients | 89,087 | 90,067 | 91,058 | 92,059 | 93,072 | 94,096 | 95,131 | 96,177 | 97,235 | 98,305 | 99,386 | 100,479 | 101,585 | 102,702 | 103,832 |
| Addressable Int-Risk, Clear Cell mRCC (Nephrectomy | 5,953 | 6,019 | 6,085 | 6,152 | 6,220 | 6,288 | 6,357 | 6,427 | 6,498 | 6,569 | 6,641 | 6,715 | 6,788 | 6,863 | 6,939 |
| | | | | | | | | | | | | | | | |
| AGS-003 Penetration in mRCC | | | | 0.2% | 2% | 8% | 15% | 19% | 20% | 20% | 20% | 20% | 20% | 20% | 20% |
| AGS-003 mRCC New Patients | | | | 12 | 124 | 503 | 954 | 1,221 | 1,300 | 1,314 | 1,328 | 1,343 | 1,358 | 1,373 | 1,388 |
| Doses in Year 1 | | | | 1.5 | 4 | 6 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| Annual Drop-Out Rate | | | | | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% |
| AGS-003 Booster Patients | | | | | 9 | 100 | 452 | 1,055 | 1,707 | 2,255 | 2,676 | 3,004 | 3,260 | 3,463 | 3,627 |
| Doses in Year 2+ | | | | | 2 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | | | | | | | | | | | | | | | |
| Price per Dose (Thousands) | | | | $ 8 | $ 8 | $ 9 | $ 9 | $ 9 | $ 9 | $ 10 | $ 10 | $ 10 | $ 10 | $ 11 | $ 11 |
| EU Newly Diagnosed Sales ($MM) | | | | $ 0.1 | $ 4 | $ 26 | $ 59 | $ 88 | $ 97 | $ 101 | $ 105 | $ 109 | $ 114 | $ 119 | $ 123 |
| EU Booster Sales ($MM) | | | | $ - | $ 0 | $ 2 | $ 14 | $ 38 | $ 64 | $ 87 | $ 106 | $ 122 | $ 137 | $ 150 | $ 161 |
| EU mRCC Sales ($MM) | | | | $ 0.1 | $ 3.7 | $ 27.9 | $ 72.5 | $ 126.5 | $ 160.4 | $ 187.3 | $ 210.8 | $ 231.6 | $ 250.5 | $ 268.1 | $ 284.8 |

| Japan Kidney Cancer | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Newly Diagnosed Kidney Cancer Patients | 17,903 | 18,028 | 18,155 | 18,282 | 18,410 | 18,538 | 18,668 | 18,799 | 18,930 | 19,063 | 19,196 | 19,331 | 19,466 | 19,602 | 19,740 |
| Addressable Int-Risk, Clear Cell mRCC (Nephrectomy | 1,196 | 1,205 | 1,213 | 1,222 | 1,230 | 1,239 | 1,248 | 1,256 | 1,265 | 1,274 | 1,283 | 1,292 | 1,301 | 1,310 | 1,319 |
| | | | | | | | | | | | | | | | |
| AGS-003 Penetration in mRCC | | | | | 0.2% | 5% | 12% | 20% | 24% | 25% | 25% | 25% | 25% | 25% | 25% |
| AGS-003 mRCC New Patients | | | | | 2 | 62 | 150 | 251 | 304 | 318 | 321 | 323 | 325 | 327 | 330 |
| Doses in Year 1 | | | | | 1.5 | 4 | 6 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| Annual Drop-Out Rate | | | | | | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% |
| AGS-003 Booster Patients | | | | | | 2 | 48 | 148 | 300 | 452 | 578 | 674 | 748 | 805 | 849 |
| Doses in Year 2+ | | | | | | 2 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | | | | | | | | | | | | | | | |
| Price per Dose (Thousands) | | | | | | $ 9 | $ 9 | $ 9 | $ 9 | $ 10 | $ 10 | $ 10 | $ 10 | $ 11 | $ 11 |
| Japan Newly Diagnosed Sales ($MM) | | | | | | $ 2 | $ 8 | $ 16 | $ 23 | $ 24 | $ 25 | $ 26 | $ 27 | $ 28 | $ 29 |
| Japan Booster Sales ($MM) | | | | | | $ 0 | $ 1 | $ 5 | $ 11 | $ 17 | $ 23 | $ 27 | $ 31 | $ 35 | $ 38 |
| Japan mRCC Sales ($MM) | | | | | | $ 1.9 | $ 8.9 | $ 20.6 | $ 33.8 | $ 41.8 | $ 48.2 | $ 53.7 | $ 58.6 | $ 63.0 | $ 67.1 |
| Japan mRCC Royalty ($MM) | 8% | | | | | $ 0.1 | $ 0.7 | $ 1.6 | $ 2.7 | $ 3.3 | $ 3.9 | $ 4.3 | $ 4.7 | $ 5.0 | $ 5.4 |

*Source: Company reports and MLV & Co. estimates.*

## APPENDIX TABLE 4

| Argos Therapeutics, Inc. (ARGS) | 2013A | | | | | 2014E | | | | | 2015E | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Income Statement ($MM) | 1QA | 2QA | 3QA | 4QA | Year | 1QA | 2QA | 3QA | 4QE | Year | 1QE | 2QE | 3QE | 4QE | Year | 2016E |
| AGS-003 mRCC US sales | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| AGS-003 mRCC EU sales | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| AGS-003 mRCC Japan royalties | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| AGS-003 mRCC Japan milestone revenue | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.0 | 1.0 | 0.0 |
| AGS-004 HIV | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | 1.5 | 1.3 | 1.0 | 0.7 | 4.4 | 0.8 | 0.5 | 0.4 | 0.0 | 1.7 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Total revenue | 1.5 | 1.3 | 1.0 | 0.7 | 4.4 | 0.8 | 0.5 | 0.4 | 0.0 | 1.7 | 0.0 | 0.0 | 0.0 | 1.0 | 1.0 | 0.0 |
| Cost of goods sold (AGS-003 mRCC US and EU) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | 0.4 | 0.9 | 5.0 |
| Gross profit | 1.5 | 1.3 | 1.0 | 0.7 | 4.4 | 0.8 | 0.5 | 0.4 | 0.0 | 1.7 | 0.0 | 0.0 | (0.4) | 0.6 | 0.1 | (5.0) |
| R&D expense | 5.2 | 6.1 | 5.6 | 7.1 | 24.0 | 8.5 | 10.6 | 13.0 | 13.3 | 45.3 | 13.3 | 13.3 | 13.3 | 13.3 | 53.2 | 53.2 |
| G&A | 1.1 | 0.9 | 1.0 | 1.6 | 4.7 | 1.9 | 1.9 | 2.3 | 2.4 | 8.5 | 2.8 | 2.9 | 3.6 | 3.7 | 13.1 | 23.0 |
| Operating expense | 6.3 | 7.0 | 6.7 | 8.7 | 28.7 | 10.4 | 12.4 | 15.3 | 15.7 | 53.9 | 16.1 | 16.2 | 16.9 | 17.0 | 66.3 | 76.2 |
| Operating profit | (4.8) | (5.8) | (5.7) | (8.0) | (24.2) | (9.6) | (12.0) | (14.9) | (15.7) | (52.2) | (16.1) | (16.2) | (17.4) | (16.5) | (66.2) | (81.2) |
| Interest income | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Interest expense | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | 0.2 | 0.2 | 0.3 | 0.9 | 0.3 | 0.3 | 1.6 | 1.6 | 3.8 | 6.0 |
| Other income (expense) | 0.4 | 0.0 | 0.0 | (0.0) | 0.3 | (0.2) | 0.1 | (0.0) | 0.0 | (0.1) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Pre-tax profit | (4.4) | (5.8) | (5.7) | (8.0) | (23.9) | (10.0) | (12.0) | (15.1) | (16.0) | (53.1) | (16.4) | (16.5) | (18.9) | (18.0) | (70.0) | (87.2) |
| Tax | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net income | (4.4) | (5.8) | (5.7) | (8.0) | (23.9) | (10.0) | (12.0) | (15.1) | (16.0) | (53.1) | (16.4) | (16.5) | (18.9) | (18.0) | (70.0) | (87.2) |
| Redeemable convertible preferred stock | (0.1) | (0.0) | (9.4) | (0.5) | (10.0) | (0.9) | 0.0 | 0.0 | 0.0 | (0.9) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **EPS** | **$ (19.91)** | **$ (25.53)** | **$ (65.23)** | **$ (36.19)** | **$ (147.37)** | **$ (1.05)** | **$ (0.61)** | **$ (0.77)** | **$ (0.82)** | **$ (2.75)** | **$ (0.66)** | **$ (0.66)** | **$ (0.76)** | **$ (0.72)** | **$ (2.81)** | **$ (2.50)** |
| Weighted average diluted shares | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 10.4 | 19.7 | 19.7 | 19.7 | 19.7 | 24.9 | 24.9 | 24.9 | 24.9 | 24.9 | 34.9 |
| AGS-003 mRCC EU and US Gross Margin | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Operating margin | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m | n/m |
| Tax rate | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

*Source: Company reports and MLV & Co. estimates*

## APPENDIX TABLE 5

| Argos Therapeutics, Inc. (ARGS) | 2013A | | | | | 2014E | | | | | 2015E | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Cash Flow ($MM)** | **1QA** | **2QA** | **3QA** | **4QA** | **Year** | **1QA** | **2QA** | **3QA** | **4QE** | **Year** | **1QE** | **2QE** | **3QE** | **4QE** | **Year** | **2016E** |
| Operating profit | (4.8) | (5.8) | (5.7) | (8.0) | (24.2) | (9.6) | (12.0) | (14.9) | (15.7) | (52.2) | (16.1) | (16.2) | (17.4) | (16.5) | (66.2) | (81.2) |
| D&A | 0.2 | 0.2 | 0.1 | 0.1 | 0.6 | 0.1 | 0.1 | 0.1 | 0.2 | 0.6 | 0.2 | 0.2 | 1.2 | 1.2 | 2.8 | 8.2 |
| Stock compensation expense | 0.2 | 0.2 | 0.2 | 0.5 | 1.1 | 0.6 | 0.6 | 0.9 | 0.9 | 3.0 | 1.0 | 1.0 | 1.0 | 1.0 | 4.0 | 4.0 |
| EBITDA | (4.5) | (5.4) | (5.3) | (7.3) | (22.5) | (8.9) | (11.2) | (13.9) | (14.7) | (48.6) | (15.0) | (15.1) | (15.2) | (14.3) | (59.4) | (69.0) |
| Cash interest | (0.0) | 0.0 | (0.0) | 0.0 | (0.0) | (0.0) | (0.0) | (0.0) | (0.3) | (0.3) | (0.3) | (0.3) | (1.5) | (1.5) | (3.5) | (5.7) |
| Cash tax | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Accounts receivable | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Inventory | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Prepaid expense | 0.1 | 0.1 | 0.1 | 0.2 | 0.4 | (0.3) | 0.3 | 0.1 | (0.4) | (0.4) | (0.0) | (0.0) | (0.1) | (0.0) | (0.1) | (0.9) |
| Account payable | 0.0 | 0.9 | (1.5) | 0.8 | 0.2 | 1.7 | (0.7) | 0.9 | (0.8) | 1.0 | 1.7 | 0.0 | 0.3 | 0.0 | 2.0 | 1.3 |
| Accrued bonuses | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.6 | (0.2) | 0.4 | 0.1 | 0.0 | 0.1 | 0.0 | 0.2 | 0.4 |
| Accrued expense | 0.2 | 0.0 | 0.1 | 0.9 | 1.2 | (0.3) | 0.3 | (0.1) | 1.0 | 0.9 | (0.2) | 0.4 | (0.5) | 1.5 | 1.2 | 3.5 |
| Prepaid royalty (Medinet) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | 0.0 | (0.0) | 0.0 | 2.4 | 2.4 | (0.5) | (0.0) | (0.3) | 0.0 | (0.8) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Cash from operations | (4.2) | (4.5) | (6.6) | (3.0) | (18.3) | (8.4) | (11.3) | (12.7) | (15.3) | (47.7) | (13.7) | (14.9) | (16.8) | (14.2) | (59.6) | (70.4) |
| Capital expenditures | (0.1) | (0.2) | (0.1) | (0.2) | (0.6) | (0.2) | (0.2) | (0.3) | (0.3) | (1.1) | (0.3) | (0.3) | (54.3) | (0.3) | (55.2) | (24.2) |
| Asset sales | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Free cash flow** | **(4.3)** | **(4.7)** | **(6.6)** | **(3.2)** | **(18.8)** | **(8.6)** | **(11.6)** | **(13.0)** | **(15.6)** | **(48.8)** | **(14.0)** | **(15.2)** | **(71.1)** | **(14.5)** | **(114.8)** | **(94.6)** |
| Cash from operations | (4.2) | (4.5) | (6.6) | (3.0) | (18.3) | (8.4) | (11.3) | (12.7) | (15.3) | (47.7) | (13.7) | (14.9) | (16.8) | (14.2) | (59.6) | (70.4) |
| Cash from investing | 2.0 | 1.8 | (0.1) | (13.8) | (10.1) | (18.2) | 3.9 | 6.6 | 20.3 | 12.6 | (0.3) | (0.3) | (54.3) | (0.3) | (55.2) | (24.2) |
| Cash from financing - debt financing | | | | | | | | | | | 0.0 | 0.0 | 54.5 | 0.0 | 54.5 | 0.0 |
| Cash from financing - debt repayment | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | (0.1) | (1.0) | (1.1) | (4.2) |
| Cash from financing - equity financing | (0.0) | (0.0) | 21.5 | 31.9 | 53.4 | 45.0 | (0.0) | 12.1 | 0.0 | 57.1 | 46.5 | 0.0 | 0.0 | 0.0 | 46.5 | 93.0 |
| F/X | (0.0) | (0.0) | 0.0 | (0.0) | (0.0) | (0.0) | 0.0 | (0.0) | 0.0 | (0.0) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net change in cash | (2.2) | (2.6) | 14.9 | 15.1 | 25.1 | 18.5 | (7.5) | 5.9 | 5.0 | 22.0 | 32.5 | (15.2) | (16.7) | (15.4) | (14.9) | (5.8) |
| Cash, beginning | 8.2 | 6.0 | 3.4 | 18.2 | 8.2 | 33.3 | 51.8 | 44.3 | 50.3 | 33.3 | 55.3 | 87.7 | 72.5 | 55.8 | 55.3 | 40.4 |
| Cash, ending | 6.0 | 3.4 | 18.2 | 33.3 | 33.3 | 51.8 | 44.3 | 50.3 | 55.3 | 55.3 | 87.7 | 72.5 | 55.8 | 40.4 | 40.4 | 34.6 |

*Source: Company reports and MLV & Co. estimates*

## APPENDIX TABLE 6

| Argos Therapeutics, Inc. (ARGS) | 2013A | | | | | 2014E | | | | | 2015E | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Balance Sheet ($MM) | 1QA | 2QA | 3QA | 4QA | Year | 1QA | 2QA | 3QA | 4QE | Year | 1QE | 2QE | 3QE | 4QE | Year | 2016E |
| Cash | -- | -- | 18.2 | 33.3 | 33.3 | 51.8 | 44.3 | 50.3 | 55.3 | 55.3 | 87.7 | 72.5 | 55.8 | 40.4 | 40.4 | 34.6 |
| Short-term investments | -- | -- | 0.0 | 13.7 | 13.7 | 31.6 | 27.5 | 19.3 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Accounts receivable | -- | -- | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Inventory | -- | -- | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Prepaid expenses and interest receivable | -- | -- | 0.6 | 0.6 | 0.6 | 0.8 | 0.8 | 0.9 | 1.3 | 1.3 | 1.3 | 1.3 | 1.4 | 1.4 | 1.4 | 2.3 |
| Deferred financing costs | -- | -- | 0.1 | 1.5 | 1.5 | 0.0 | 0.0 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| Other receivables | -- | -- | 0.7 | 0.4 | 0.4 | 0.6 | 0.3 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Current assets | -- | -- | 19.5 | 49.5 | 49.5 | 84.8 | 72.9 | 70.9 | 57.1 | 57.1 | 89.6 | 74.3 | 57.7 | 42.3 | 42.3 | 37.4 |
| PP&E, net | -- | -- | 1.5 | 1.6 | 1.6 | 1.7 | 1.8 | 4.5 | 4.7 | 4.7 | 4.8 | 5.0 | 58.1 | 57.1 | 57.1 | 73.1 |
| Long-term investment (lease security deposit) | -- | -- | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.3 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other assets | -- | -- | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 2.1 | 2.1 | 3.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Total assets** | **--** | **--** | **21.0** | **51.1** | **51.1** | **86.5** | **74.7** | **76.8** | **63.8** | **63.8** | **97.4** | **79.3** | **115.8** | **99.4** | **99.4** | **110.5** |
| Accounts payable | -- | -- | 0.5 | 1.3 | 1.3 | 3.0 | 2.2 | 3.1 | 2.4 | 2.4 | 4.0 | 4.1 | 4.3 | 4.4 | 4.4 | 5.7 |
| Accrued bonuses | -- | -- | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.6 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 | 0.6 | 0.6 | 0.9 |
| Accrued expense | -- | -- | 0.9 | 1.8 | 1.8 | 1.3 | 1.5 | 1.1 | 2.2 | 2.2 | 2.0 | 2.3 | 1.8 | 3.4 | 3.4 | 6.9 |
| Current portion of notes payable | -- | -- | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Current liabilities | -- | -- | 1.4 | 3.2 | 3.2 | 4.3 | 3.8 | 4.9 | 4.9 | 4.9 | 6.4 | 6.8 | 6.7 | 8.3 | 8.3 | 13.5 |
| Prepaid royalty (Medinet) | | | | | | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Long-term portion of notes payable | -- | -- | 0.0 | 7.0 | 7.0 | 7.2 | 7.3 | 19.6 | 21.8 | 21.8 | 21.8 | 21.9 | 34.5 | 33.6 | 33.6 | 30.0 |
| Long-term portion of facility lease obligation | -- | -- | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 2.6 | 2.6 | 2.6 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Deferred liability | -- | -- | 0.0 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 |
| Other liabilities | -- | -- | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | (3.0) | 38.9 | 38.8 | 38.8 | 31.5 |
| **Total liabilities** | **--** | **--** | **1.5** | **13.2** | **13.2** | **14.6** | **14.2** | **30.1** | **32.3** | **32.3** | **31.3** | **28.8** | **83.2** | **83.9** | **83.9** | **78.1** |
| **Redeemable convertible preferred stock** | **--** | **--** | **87.3** | **113.7** | **113.7** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** |
| **Shareholders' equity** | **--** | **--** | **(67.8)** | **(75.8)** | **(75.8)** | **71.9** | **60.6** | **46.7** | **31.5** | **31.5** | **66.1** | **50.5** | **32.6** | **15.6** | **15.6** | **32.4** |
| **Total liabilities & equity** | **--** | **--** | **21.0** | **51.1** | **51.1** | **86.5** | **74.7** | **76.8** | **63.8** | **63.8** | **97.4** | **79.3** | **115.8** | **99.4** | **99.4** | **110.5** |

*Source: Company reports and MLV & Co. estimates*

## IMPORTANT DISCLOSURES

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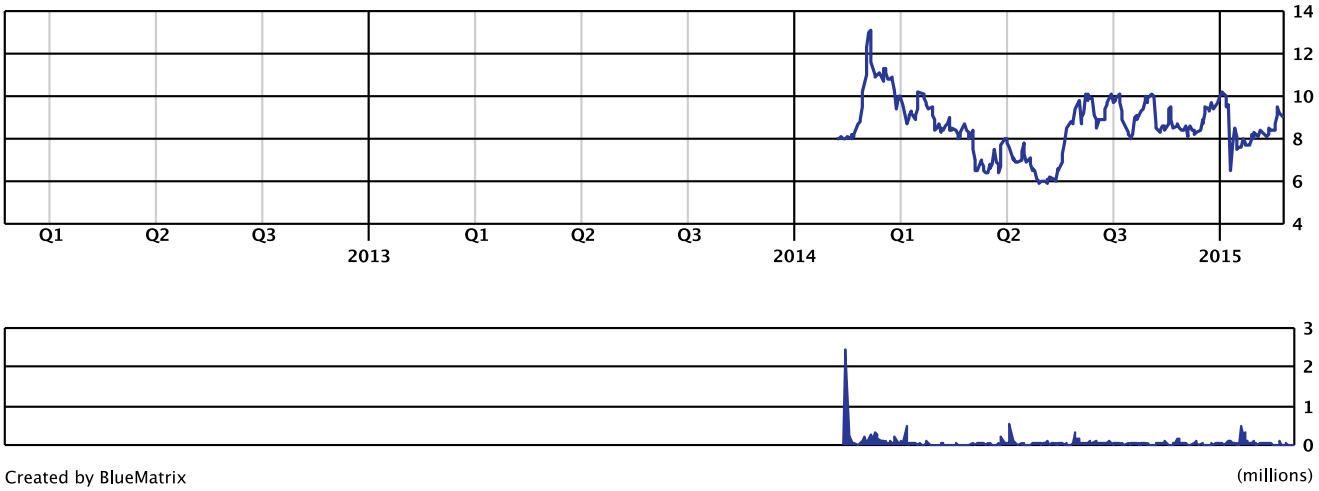
**Argos Therapeutics, Inc. (ARGS): Share Price (in USD) and Volume History as of 02-24-2015**

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|---|---|---|---|---|
| Rating | Count | Percent | Count | Percent |
| BUY | 120 | 65.57% | 55 | 30.05% |
| HOLD | 63 | 34.43% | 19 | 10.38% |
| SELL | 0 | 0.00% | 0 | 0.00% |

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