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April 18, 2023
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Abeona Therapeutics Inc.

(ABEO-NASDAQ)

ABEO: Initiating Coverage of Abeona Therapeutics Inc.; Using Gene Therapy to Treat Orphan Diseases…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB-101 and selling a PRV, ABEO is valued at $10.00/share. This model is highly dependent upon the continued clinical and commercial success of EB-101 and will be adjusted accordingly based on future results.

Current Price (04/18/23)	$3.00
Valuation	**$10.00**

OUTLOOK

We are initiating coverage of Abeona Therapeutics, Inc. (ABEO) with a valuation of $10.00. Abeona is a biopharmaceutical company developing cell and gene therapies for rare genetic diseases. The company recently announced positive Phase 3 results for its lead development product, EB-101, and we anticipate a Biologics License Application (BLA) to be submitted to the FDA in late second quarter or early third quarter 2023. EB-101 is an autologous cell therapy in development for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). The drug has been granted rare pediatric disease designation by the FDA and thus may be eligible for a priority review voucher (PRV) if approved. PRV's have recently sold for $100 million.

SUMMARY DATA

52-Week High	**$6.81**
52-Week Low	**$2.25**
One-Year Return (%)	**-55.21**
Beta	**1.26**
Average Daily Volume (sh)	**91,957**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$53**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**38**
Insider Ownership (%)	**2**
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	**-1.6**
P/E using 2024 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Blend**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0.3 A	1.0 A	0.0 A	0.1 A	1.4 A
2023	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E
2024					11.0 E
2025					44.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$3.54 A	-$2.08 A	-$1.48 A	-$0.08 A	-$5.53 A
2023	-$0.68 E	-$0.70 E	-$0.63 E	-$0.64 E	-$2.65 E
2024					-$2.15 E
2025					-$0.94 E

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WHAT'S NEW

Initiating Coverage



Source: Abeona Therapeutics Inc.

We are initiating coverage of Abeona Therapeutics Inc. (ABEO) with a valuation of $10.00. Abeona is a biopharmaceutical company developing cell and gene therapies for rare genetic diseases. Its lead clinical program, EB-101, is an autologous cell therapy in development for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). In November 2022, Abeona announced positive topline results from the Phase 3 VIITAL™ study showing it met the two co-primary endpoints while exhibiting a clean safety and tolerability profile. We anticipate the company filing a Biologics License Application (BLA) late in the second quarter or early in the third quarter of 2023. The company also recently announced lead development candidates for its adeno-associated virus (AAV) platform; ABO-504 for Stargardt disease, ABO-503 for X-linked retinoschisis (XLRS), and ABO-505 for autosomal dominant optic atrophy. We anticipate the company conducting pre-IND meetings with the FDA regarding those programs in the second quarter of 2023.

BLA Set to be Filed in late 2Q or early 3Q 2023

The Phase 3 VIITAL study examined 43 large chronic wound pairs in 11 subjects with RDEB. The study met its two co-primary endpoints showing statistically significant, clinically meaningful improvements in wound healing and pain reduction compared to control. In addition, there were no treatment-related serious adverse events, no instances of positive replication-competent retrovirus results, and no systemic immunologic responses. Based on these results, we anticipate the company filing a BLA with the FDA late in the second quarter or early third quarter of 2023.

Potential $1.5 Billion to $2.7 Billion Opportunity

RDEB is an ultra-orphan indication with an estimated U.S. prevalence of approximately 3,850 patients. If 40% of the eligible patients each received two cycles of EB-101, at an estimated price in the range of $500K to $900K per treatment, it represents a potential $1.5 billion to $2.7 billion opportunity in the US market. Given how rare RDEB is and the estimated cost of wound care every year (~$300K), we are confident there would be little pushback from payers.

Priority Review Voucher Could Extend Cash Runway

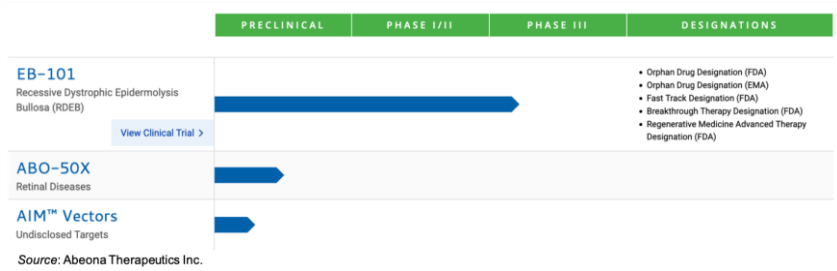
In November 2022, Abeona announced a private placement that generated gross proceeds of $35 million. We estimate this will extend the company's cash runway into the third quarter of 2024 and past a potential FDA approval of EB-101. Approval of EB-101 may also include a priority review voucher (PRV) since the drug has rare pediatric designation from the FDA. PRV's are fully transferable and a number of them have recently sold for approximately $100 million.

AAV Pipeline Adds Potential Upside

In addition to EB-101, Abeona is developing novel adeno-associated virus (AAV) capsids to deliver genetic payloads that have improved cell/tissue tropism and reduced immune response, which may render them able to be re-dosed in those with prior AAV therapy. The company recently nominated three development candidates and we anticipate pre-IND meetings with FDA for those programs occurring during the second quarter of 2023.

INVESTMENT THESIS

Abeona Therapeutics Inc. (ABEO) is a biopharmaceutical company developing cell and gene therapies for rare genetic diseases. The lead clinical program is EB-101, which is an autologous, gene-corrected cell therapy for the treatment of the ultra-rare orphan disease recessive dystrophic epidermolysis bullosa (RDEB). In November 2022, the company announced positive topline results from the Phase 3 VIITAL™ trial, which showed that EB-101 met its two co-primary efficacy endpoints demonstrating statistically significant, clinically meaningful improvements in wound healing and pain reduction. The treatment was also shown to be safe and well-tolerated as there were no reports of treatment-related serious adverse events. Based on these results, we anticipate the company filing a Biologics License Application (BLA) with the FDA late in the second quarter or early in the third quarter of 2023. Approval of EB-101 may also include a priority review voucher (PRV). PRVs are fully transferrable and have recently been sold for approximately $100 million. Lastly, the company's proprietary capsids and gene constructs (including the AIM™ adeno-associated virus (AAV) capsid library) are being developed for ophthalmic conditions. The novel capsids are designed to have highly selective tissue/cell tropism and reduced immune response, which could offer the potential for re-dosing.



Source: Abeona Therapeutics Inc.

EB-101

EB-101 is an autologous, gene corrected cell therapy that contains a functioning *COL7A1* gene inserted into a patient's keratinocytes (skin cells) using a retrovirus. It is being developed for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), an ultra-orphan genetic disease in which patients have one or more defects in the *COL7A1* gene. This results in an inability to produce functional type VII collagen protein, which is involved in anchoring the skin's dermal and epidermal layers.

RDEB

RDEB belongs to a group of heterogeneous inherited skin disorders (epidermolysis bullosa, EB) that are characterized by defective epithelial adhesion, skin fragility, and the development of skin lesions following minor stress to the skin. These traumas often lead to chronic unhealing ulcers, as exhibited on the patient in the following figure.


Source: Abeona Therapeutics Inc.

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There are currently 21 different disease-causing variants associated with an EB phenotype (Has *et al*., 2018). RDEB is caused by mutations in the *COL7A1* gene, which encodes for type VII collagen. The gene for type VII collagen comprises approximately 32 kb on human chromosome 3 and encodes for a protein of 2,944 amino acids. The expression of type VII collagen is tissue specific and occurs primarily in select epithelial cells, including skin, and its expression can be modulated by a number of cytokines, including transforming growth factor beta (TGF-β).

Type VII collagen is produced in epidermal keratinocytes and following translation three type VII collagen polypeptide chains associate through the carboxy-terminal ends to form a homotrimeric molecule. Following secretion into the extracellular matrix, two type VII collagen molecules align into anti-parallel dimers, which in turn aggregate to form anchoring fibrils. Type VII collagen is the major component of anchoring fibrils in the dermal-epidermal basement membrane (Chung *et al*., 2010).

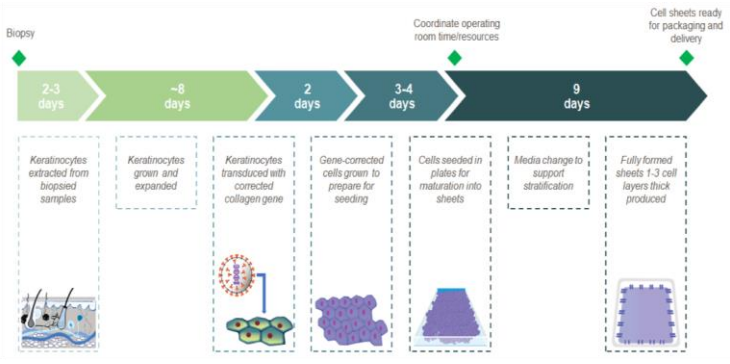
Immunofluorescence of skin from RDEB patients show a lack of anchoring fibrils and type VII collagen, suggesting that mutations in type VII collagen are responsible for the disease (Bruckner-Tuderman *et al*., 1989). Further analysis of 19 families with RDEB showed a robust linkage between the type VII collagen gene and disease phenotype (Hovnanian *et al*., 1992). A large number of mutations in the *COL7A1* gene have been identified, including small insertions/deletions, splice junction mutations causing a frameshift of translation, and premature termination codon-causing mutations that can lead to a complete absence of type VII collagen protein (Christiano *et al*., 1997).

In addition to blister and lesion formation, RDEB patients are also at an increased risk of extracutaneous manifestations including involvement of the gastrointestinal tract, genitourinary tract, kidneys, and heart (Fine *et al*., 2009). In addition, patients are at an increased risk of glomerulonephritis, renal amyloidosis, IgA nephropathy, and cardiomyopathy (Fine *et al*., 2004; Fine *et al*., 2008). The incidence of squamous cell carcinoma (SCC) is increased in RDEB patients and is typically seen at an earlier age than in non-RDEB individuals (Montaudié *et al*., 2016).

There are no definitive treatments for RDEB and symptom relief is at the core of clinical management. The prevention of blisters and ulcers is the most important aspect of treatment (Pope *et al*. 2012). This includes daily changing of the wound dressing along with the application of topical antibiotics. Even with meticulous care of the wounds, infections are inevitable and can require systemic antibiotic therapy. For patients with severe disease, management of secondary symptoms requires a collaboration among multiple different specialists (Bruckner-Tuderman *et al*., 2010). The estimated annual cost for wound dressings alone for an RDEB patient is approximately $300,000 per year (Harricharan *et al*., 2021).

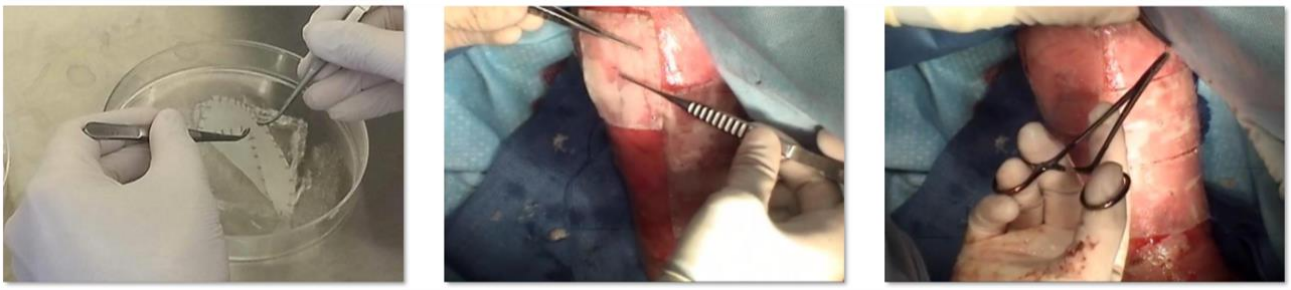
EB-101

The purpose of EB-101 is to restore functional collagen VII to patient's own skin cells so that wounds can properly heal and have less chance of recurring in the future. The figure below gives an overview of the process associated with treating a patient with EB-101. Keratinocytes are taken from a skin biopsy and grown in cell culture for a little over a week. The cells are then transduced with a corrected copy of the *COL7A1* gene, carried within a retroviral vector, and the gene-corrected cells are then allowed to propagate. The cells are seeded in plates to promote "sheet" formation and the fully formed "skin sheets" are approximately 1-3 cells thick and ready to be transplanted onto the patient.



Source: Abeona Therapeutics Inc.

EB-101 is administered using a standard surgical procedure that is akin to a skin graft. The following images show the procedure for applying EB-101. While the wound bed is being prepared, the surgeon prepares EB-101 for transplant. The skin sheets are then applied to the wound and sutured in place. The wound is then treated with antibiotics and wrapped in gauze.

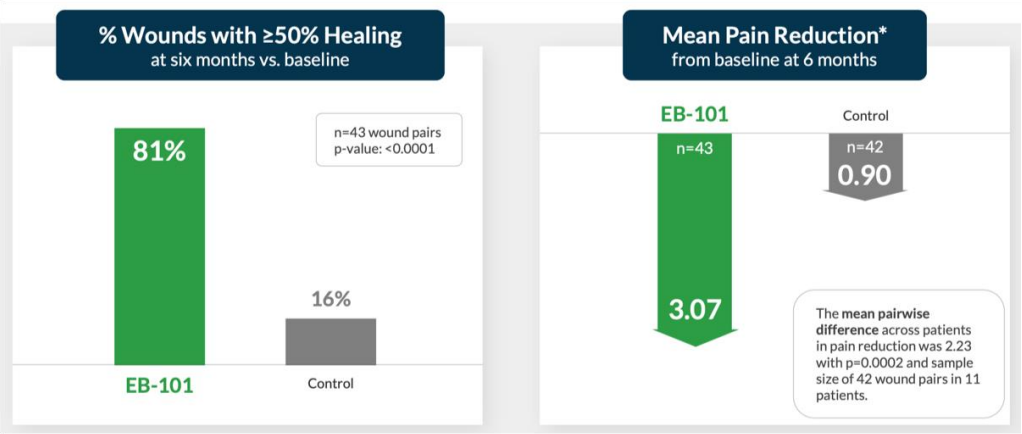


Source: Abeona Therapeutics Inc.

Phase 3 VIITAL Study Results

In November 2022, Abeona announced positive topline results for the Phase 3 VIITAL study of EB-101 for the treatment of large chronic RDEB wounds (NCT04227106). The study evaluated the safety and efficacy of EB-101 in 43 large chronic wound pairs in 11 subjects with RDEB. Each of the wounds measured > 20 cm^2 of surface area and had remained open for at least six months and a maximum of 21 years. The co-primary endpoints of the study were: 1) the proportion of RDEB wound sites with ≥ 50% healing from baseline when comparing treated with matched untreated wound sites at the six-month timepoint, and 2) pain reduction associated with wound dressing change that was assessed through the scores of the Wong-Baker FACES scale by comparing treated and matched untreated wounds at the six-month timepoint. An exploratory endpoint was to determine the percentage of wound sites with ≥75% wound healing at the six-month timepoint. The study also allowed for wounds not included in the primary efficacy analysis to be treated with EB-101.

The following graphs show the results for the study's co-primary endpoints. Eighty-one percent of the wounds treated with EB-101 showed ≥ 50% healing at the six-month timepoint compared to only 16% of control wounds (*P*<0.0001). The mean pain reduction for wounds treated with EB-101 was 3.07 points on the Wong-Baker FACES scale, compared to just 0.90 points for control wounds (*P*=0.0002).

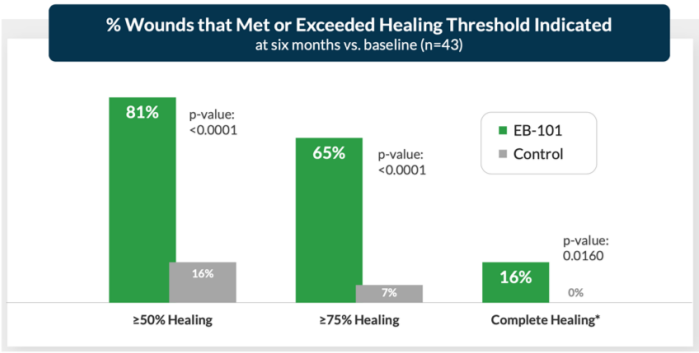


Source: Abeona Therapeutics Inc.

Importantly, EB-101 showed the greatest pain reduction in wounds that had the highest baseline pain. For all treated wounds with a baseline pain ≥ 6 (n=27), the mean reduction in pain was 5.70 while for all treated wounds (n=53) the mean pain reduction was 3.51.

Compared to control, EB-101 showed significantly improved wound healing regardless of the level of healing. The following figure shows that of all the wounds that were treated with EB-101, 65% of those met the threshold of ≥ 75% healing and 16% reached the level of complete healing. This is in contrast to 0% of control

wounds that reached the level of complete healing. There was a very stringent criteria applied in order to score wounds as completely healed, including complete re-epithelialization with no drainage or erosion and no major crusting as judged by the investigator.



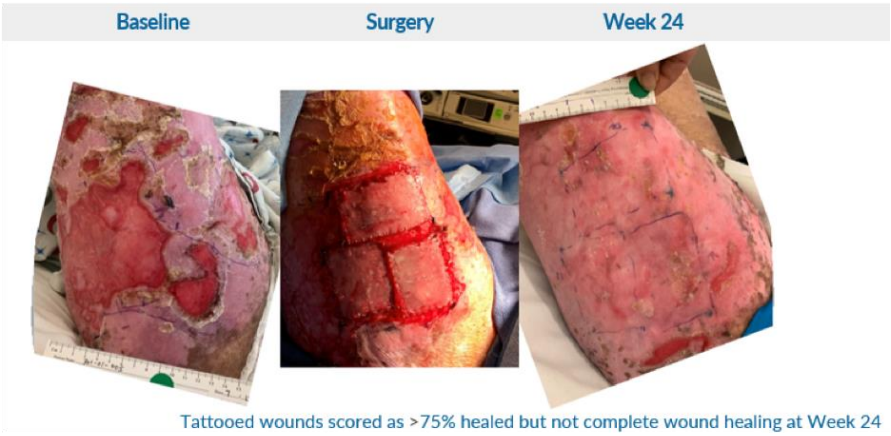
Source: Abeona Therapeutics Inc.

The following images give a representation of what wounds scored as ≥ 75% healing and complete healing look like. Wound B4 was scored as ≥ 75% healed at Week 24, while wound E9 was scored as completely healed at Week 24.



Source: Abeona Therapeutics Inc.

While some wounds may appear fully closed, they still may not be counted as completely healed. The following image gives an example of a wound that appeared to be fully closed at Week 24, however it was still scored as ≥ 75% healed. The image shows some crust formation at Week 24, which precluded this wound from being scored as completely healed. As a reminder, 0% of the control large-chronic wounds showed spontaneous complete wound healing at Week 24, which underscores the challenging nature of the wound type being treated.



Source: Abeona Therapeutics Inc.

In regards to safety and tolerability, EB-101 was well tolerated and there were no treatment-related serious adverse events (SAEs) and no safety signals observed in the VIITAL study or during the clinical development program. In addition, there were no deaths, no instances of positive replication-competent retrovirus results, no systemic immunologic responses, and no SCC at treatment sites after treatment with EB-101. Four subjects (4/11, 36.4%) reported related treatment emergent adverse events (TEAEs), including procedural pain, muscle spasms, and pruritis. Eight subjects (72.2%) reported infections that were unrelated to EB-101 while wound related TEAEs were reported in 9/100 (9.0%) of wounds.

The positive results of the VIITAL study demonstrate that EB-101 is effective in promoting wound healing in RDEB patients and the company will be submitting these results, along with results from the earlier Phase 1/2 clinical trial, as part of a biologics licensing application (BLA) that we anticipate being filed late in the second quarter or early third quarter of 2023. We also anticipate the company presenting additional data from the VIITAL study in an oral presentation at the inaugural International Societies for Investigative Dermatology (ISID) meeting in May 2023.

Phase 1/2 Study of EB-101

The VIITAL study was a follow up to the Phase 1/2 clinical trial of EB-101 that that was initiated in 2013 (NCT01263379). A total of seven patients were enrolled with 42 treated wounds (Eichstadt *et al*., 2019). The results showed that at three and six months, 95% of treated sites had ≥ 50% healing, compared to 68% at 12 months, 71% at two years, and 80% at three years. The percentage of wounds that showed ≥ 75% healing was 82% at three months, 66% at six months, 39% at 12 months, 58% at two years, and 70% at three years.

Compared to control wounds, wounds treated with EB-101 showed a statistically significantly higher percentage of wound healing ≥ 50%. At six months, 95% (36/38) of EB-101 treated wounds showed ≥ 50% wound healing compared to 0% (0/6) of untreated control wounds (P<0.0001). This trend continued at both one year (68% of EB-101 treated vs. 17% of control wounds; P=0.025) and two year (71% of EB-101 treated vs. 17% of control wounds; P=0.019) follow up.

The efficacious wound healing was accompanied by a reduction in pain. Prior to treatment with EB-101, pain was reported in 53% (20/38) of wound sites. At EB-101 treated sites with ≥ 50% wound healing, pain was reported in 0% (0/26) of sites at one year, 4% (1/27) at 2 years, and 0% (0/16) at 3 years. Similar results were seen with improvement in itch, which was present in 61% (23/38) of wounds at baseline compared to 19% (5/26) of treated sites at one year, 7% (2/27) at two years, and 0% (0/16) at three years.

No serious related adverse events were reported during the trial and there was no evidence of systemic immune symptoms and no development of SCC at any treated site. In addition, replication-competent retrovirus and cytotoxic T cell assays were negative at all time points assayed. All local wound infections were treated with topical or oral antibiotics and no participants developed systemic infections.

A long-term safety and efficacy follow up for the Phase 1/2 trial was published in 2022 (So *et al*., 2022). The mean follow-up was 5.9 years, with a range of 4-8 years. At year five, 70% (21/30) of EB-101 treated sites had ≥ 50% wound healing and 63% (19/30) of treated sites had ≥ 75% wound healing. Five years after treatment, pain and itch were both reported at 33% (12/36) of treated sites, which was a decrease from 53% and 61%, respectively. Both pain and itch were recorded as a binary “yes/no” response, thus any decrease in the magnitude of pain was not reflected in the study results.

Wound healing ≥ 50% was associated with significant long-term clinical benefits. At year five, pain was reported at 0% of sites that achieved ≥ 50% wound healing. This is in contrast to 67% (6/9) sites that had < 50% wound healing (P<0.001). None of the sites with ≥ 50% wound healing at year five were pruritic, in contrast to 67% (6/9) of sites with < 50% wound healing at year five that were pruritic.

In August 2020, patients began completing annual questionnaires regarding pain at grafted sites compared to baseline on a seven-point Likert-type scale. At the last follow-up, there was a significant reduction in pain at grafted sites compared to control sites. Compared to baseline, pain was “very much improved” or “much improved” at 47.2% (17/36) of grafted sites and “a little improved” at 16.7% (6/36) of grafted sites (P=0.003). None of the treated wounds had “worse” pain compared to baseline. While the grafted sites continued to show

improvement in pain, 67% (4/6) of control wounds had “no change” in pain and 33% (2/6) had “worse” pain than baseline.

The long-term safety data showed that there were no serious adverse events related to study treatment. Two participants died during follow up from RDEB disease progression, one subject from sepsis and one from failure to thrive due to severe malnutrition. Two subjects developed cutaneous SCCs but neither of which were deemed to be related to grafting as all occurred distant from the grafted sites. Serum samples were analyzed at months 1, 3, 6, and then annually thereafter for the presence of replication competent retrovirus (RCR). No evidence of RCR was ever identified in 41 samples.

The data from the Phase 1/2 study is highly encouraging as it shows that long-term pain reduction is possible with EB-101 and that there are no worrying safety signals at up to five years following treatment. When combined with the data from the VIITAL study, we believe the clean safety record and sufficient positive data for EB-101 is more than sufficient to warrant approval of the product.

Other RDEB Therapies in Development

Krystal Biotech – Beremagene Geperpavec (B-VEC)

Krystal’s lead development product, B-VEC, utilizes the company’s engineered herpes simplex virus-1 (HSV-1) engineered viral platform. The HSV-1 vector is designed to be replication incompetent, which reduces cytotoxicity and the potential for cell to cell spread, while utilizing the advantages of HSV-1, including immune-evasion, large payload capacity, and broad tropism. B-VEC is a replication incompetent HSV-1 vector that contains the *COL7A1* gene. It is applied via a topically-administered gel, where B-VEC enters the compromised skin of RDEB patients and transduces both keratinocytes and fibroblasts. B-VEC is episomally maintained and thus once the transduced cells die during normal tissue turnover the episome is lost. How this may affect durability is unclear at this time.

B-VEC was evaluated in the Phase 3 GEM-3 study (Guide *et al*., 2022). A total of 31 patients with genetically confirmed DEB were enrolled. Two cutaneous wounds were identified for each patient, one was treated with B-VEC and the other with placebo. There was a randomized, double blind 6-month treatment period that consisted of once weekly treatment until wound closure with the treatment being resumed if the wound reopened. Secondary wounds for some patients were also treated in an open-label 6-month treatment period. The primary efficacy endpoints were complete wound healing (defined as 100% wound closure specified as skin re-epithelialization without drainage) at Week 22 and Week 24 or at Week 24 and Week 26. Secondary endpoints included complete wound healing at Week 8 and Week 10 or at Week 10 and Week 12. Additional secondary endpoints included the mean change in pain severity (VAS or FLACC-R scale) associated with wound dressing changes.

Results showed that treatment with B-VEC resulted in significantly greater complete wound healing than placebo. At the 6-month time point, 67% of B-VEC treated wounds showed complete wound healing compared to 22% of placebo treated wounds (P=0.002). In addition, at the 3-month time point 71% of B-VEC treated wounds showed complete wound healing compared to 20% of placebo treated wounds (P<0.001). Durability of response was defined as achieving complete healing at both three months and six months. This was achieved by 49.7% of B-VEC treated wounds and 7.1% of placebo treated wounds.

B-VEC was generally well tolerated with no serious adverse events related to study drug. There were also no significant immunologic reactions. In addition, treatment response to B-VEC was not associated with HSV-1 serostatus at baseline or with COL7 seroconversion.

Based on the results of the GEM-3 trial, Krystal submitted a BLA to the FDA in June 2022. The BLA was accepted in August 2022, granted priority review, and given a PDUFA date of February 17, 2023. In January 2023, Krystal announced that the FDA had extended the PDUFA date to May 19, 2023 with proposed labeling discussions no later than April 20, 2023. The company is expected to submit a marketing authorization application (MAA) with the European Medicines Agency (EMA) in the second half of 2023.

Amryt Pharma Plc – Oleogel-S10

Amryt is developing Oleogel-S10 for the treatment of RDEB. Oleogel-S10 is an herbal medicinal product that contains birch triterpenes from birch bark. The drug is thought to accelerate wound closure through effects of birch triterpenes on inflammation and epithelialization involving keratinocyte differentiation and migration.

Results from the Phase 3 EASE trial (NCT03068780) were announced in October 2020 and published in 2022 (Kern *et al*., 2023). A total of 223 patients with different forms of EB (including RDEB) were randomized to receive Oleogel-S10 or placebo in a 1:1 manner. Study gel was applied to all wounds at least every four days. The primary endpoint was the proportion of patients with first complete closure of target wound within 45 days.

The proportion of RDEB patients with first complete closure of target wound within 45 days was 44.0% in the Oleogel-S10 group compared to 26.2% in the control group (*P*=0.008). In addition, a greater reduction in pain associated with dressing changes was seen in the Oleogel-S10 group at each time point compared with the control group.

Amryt submitted an NDA in 2021 and received a complete response letter in February 2022, with the FDA indicating that Amryt would need to submit additional confirmatory evidence of effectiveness for Oleogel-S10.

Amryt was acquired by Chiesi Farmacuetical in January 2023 for up to $1.48 billion.

BridgeBio Pharma/Phoenix Tissue Repair – PTR-01

PTR-01 is a protein replacement therapy that uses a recombinant collagen type VII for the treatment of RDEB. In four animal models, PTR-01 was shown to selectively anchor to the skin and replace absent collagen type VII, thereby improving tissue structure, disease presentation, and survival.

In May 2022, the companies announced data from the Phase 2 clinical trial of PTR-01. It was an open label study in which PTR-01 was given once per week for four weeks and then every other week for 14 weeks. Results showed that over 80% of target wounds (21/26) showed ≥ 50% wound healing at the end of treatment (Day 120) compared to baseline. The response was seen in many different wound types: large (89%) and small (77%) as well as recurrent (86%) and chronic (75%). Clinician assessment was scored on a 7-point scale. By Day 15, 58% (15/26) met the response criteria of ≥ 2-point increase on the wound-specific scale and at Day 120 69% (18/26) met the response criteria. All patients that completed the study (n=5) reported a decrease in pain over the course of PTR-01 treatment. Lastly, there was a rapid deposition of recombinant collagen type VII at the dermal-epidermal junction during the loading phase (first 28 days of treatment) and remained present up to three months after treatment.

Castle Creek Biosciences – FCX-007 (D-Fi)

Castle Creek is developing FCX-007 (D-Fi; dabocemagene autoficel) as an ex vivo, autologous cell-based gene therapy. The company utilizes a self-inactivating lentiviral vector that contains the *COL7A1* gene to transduce a patient's own fibroblasts. The fibroblasts are then locally administered intradermally to sites of active wounds.

FCX-007 was evaluated in a Phase 1/2 clinical trial in 2021 (NCT02810951). The trial evaluated six patients with RDEB. The primary outcome was safety with a secondary endpoint of complete wound closure at all post-baseline visits. Results showed that of treated wounds analyzed, complete closure occurred in 40% (n=10), 80% (n=10), 75% (n=4), and 50% (n=6) at Week 4, Week 12, Week 25, and Week 52, respectively. This is in contrast to untreated wounds, which showed complete closure in 0% (n=10), 0% (n=9), 0% (n=4), and 16.7% (n=6) at Week 4, Week 12, Week 25, and Week 52, respectively. FCX-007 was well tolerated with only one report of temporary redness or discoloration at the injection site.

Castle Creek has advanced FCX-007 to a Phase 3 clinical trial (NCT04213261). It is a multi-center, within-patient randomized, controlled, open label trial that will enroll approximately 24 patients living with RDEB. Each target wound on a patient will be paired with an untreated wound, with up to three wound pairs identified for each participant. The primary outcome of the trial is complete wound closure of the first wound pair at Week 24.

In October 2021, the company announced that the FDA awarded a $1.825 million research grant from the Office of Orphan Products Development to support the Phase 3 clinical trial.

RDEB Market Opportunity

RDEB is an orphan indication. There are only approximately 3,850 RDEB individuals estimated to be living in the U.S. (Eichstadt *et al*., 2019). However, given that there are no approved therapies beyond supportive care we estimate that a large segment of the RDEB population will seek out FDA approved therapies. The cost for wound care each year for an RDEB patient is estimated to be approximately $300,000 ((Harricharan *et al*., 2021), thus we believe there is strong support for a therapy such as EB-101 commanding a premium price.

We conservatively estimate that approximately half of RDEB patients would have access to treatment and that approximately 80% would choose EB-101 to treat their large chronic wounds. This leads to a target treatment population of approximately 1500. We estimate that the company could charge between $500,000 and $900,000 per treatment, and that each patient would likely require two treatments to address each of their chronic wounds. Thus, we estimate the addressable market to be approximately $1.5 billion to $2.7 billion in the U.S.

As discussed previously, there are other RDEB therapies under development. Of particular interest is B-VEC, since it is the closest to obtaining regulatory approval. However, given the range of wound types/sizes most patients experience we don't believe there will be any limitation to using multiple types of RDEB therapies. For examples, a patient may choose to treat smaller acute wounds with B-VEC while opting to treat larger, chronic wounds with EB-101. Thus, we don't view the $1.5 billion to $2.7 billion opportunity as a zero-sum game. Rather, it is part of an even larger addressable market when factoring in the care of large chronic wounds and smaller recurrent wounds.

AIM™ Vector / ABO-50X

Abeona has an exclusive license to an international patent family that covers novel adeno-associated virus (AAV) capsids (AIM™ capsids) that could be used to deliver a wide variety of therapeutic transgenes to treat genetic diseases. The AIM vectors are non-replicating and have shown an ability to evade immune responses generated by exposure to naturally occurring AAV. The company's AIM capsid library includes vectors that can selectively target genetic payloads to the central nervous system, lungs, eye, muscle, liver, and other tissues.

The company is currently testing several vectors in preclinical studies as part of the ABO-50X program. A lead capsid (AAV204) has been identified that demonstrates robust transduction of retinal cells. Data from mouse studies showed that intravitreal administration of AAV204 resulted in broad retinal expression that penetrated to the photoreceptor and retinal pigmented epithelium layers. In addition, non-human primate studies showed that intravitreal administration resulted in broad transgene expression in the peripheral retina as well as intense expression in the fovea 25 days following administration. Para-retinal administration showed transduction of photoreceptor cells in the fovea as well as strong expression in retinal ganglion cells throughout the retina.

Abeona recently announced three preclinical programs for different serious eye diseases, including:

ABO-504 for Stargardt disease – This is a rare genetic eye disease that is typically caused by a mutation in the *ABCA4* gene and results in a loss of central vision and sensitivity to light. The ABCA4 protein is expressed in the retina's light receptor cells and is critical for the clearance of potentially toxic intermediates of the visual cycle. Its absence leads to accumulation of these products and can lead to photoreceptor cell death. Therapeutic development for Stargardt disease has been hampered by the size of the ABCA4 coding sequence, which exceeds the carrying capacity of a standard AAV viral genome. ABO-504 uses a dual AAV vector strategy to deliver a full-length *ABCA4* gene using the Cre-LoxP recombinase system. Abeona has demonstrated full-length ABCA4 protein production in vivo in mouse disease models of Stargardt disease. The disease affects approximately 1 in 8,000 to 1 in 10,000 people in the U.S.

ABO-503 for X-linked retinoschisis (XLRS) – This is a rare genetic eye disease that is caused by a mutation in the *RS1* gene on the X chromosome. It has an estimated prevalence of approximately 35,000 individuals in the U.S. and E.U. combined. The RS1 gene encodes for retinoschisin, which is critical for the development and maintenance of the retina. Without retinoschisin, the layers of the retina split, which leads to vision loss. ABO-503 consists of a functional human *RS1* gene packaged inside capsid AAV204. The vector allows for pararetinal injection, which led to high transduction efficiency in non-human primate (NHP) studies.

ABO-505 for autosomal dominant optic atrophy (ADOA) – This is a rare genetic eye disease that results in progressive and irreversible vision loss in both eyes starting during childhood. Most cases are caused by mutations in the *OPA1* gene. The OPA1 protein stabilizes the inner mitochondrial membrane, thus the vision problems experienced by those with ADOA are due to mitochondrial dysfunction. This dysfunction results in a progressive loss of nerve cells within the retina and then atrophy of the optic nerve. ADOA affects approximately 1 in 30,000 people worldwide. ABO-505 consists of a function *OPA1* gene packaged inside capsid AAV204.

The company has begun submitting pre-IND meeting requests with the FDA for those candidates and we anticipate meetings taking place in the second quarter of 2023. In addition, we anticipate the company presenting new preclinical data for those programs at a scientific meeting in the second quarter of 2023.

Manufacturing Facility

Abeona has a 16,000+ square foot cGMP manufacturing facility located in Cleveland, OH. This includes a 6,000 square foot state-of-the-art cGMP production facility for the manufacturing of cell and gene therapies and an 8,000 square foot state-of-the-art laboratory space for quality control, process development, and assay development. Having this facility under the company's control allows for great supply chain control, tighter quality control testing, flexible supply capacity, greater control on production costs, and enhanced manufacturing efficiency so that commercial demand can be met in the event EB-101 or other development therapies receive marketing approval.

EB-101 is manufactured as a multilayer cellular sheet containing corrected keratinocytes that is secured to a petrolatum gauze backing with surgical hemoclips. The retroviral vector is a key component of the manufacturing process. The cGMP manufacturing process for the vector was transferred to the Cleveland, OH facility and the company has produced three cGMP lots for analytical and clinical comparability.

In addition to EB-101 manufacturing, Abeona has established AAV vector manufacturing capabilities using the triple plasmid transfection method. AAV-293 cells are transfected with three DNA plasmids encoding the specific therapeutic gene sequence, the capsid coding sequence, and helper sequences. Following transfection, each cell produces AAV vectors that are harvested, purified, and filtered in accordance with cGMP protocols.

Intellectual Property

Abeona owns or has license agreements in place for the following intellectual property protection:

RDEB: The company licensed a patent family from Stanford University that covers EB-101 and its use in the treatment of RDEB. Patents covering EB-101 have been granted by the European Patent Office (EP3400287B1) and are expected to expire in 2037. Patent applications in the U.S. are pending and, if granted, would be expected to have an expiration date in 2037. Abeona has also filed for patent protection concerning the packaging and transport of EB-101 and, if granted, would be expected to expire in 2040.

AIM Capsids: Abeona has a worldwide exclusive license to an international patent family from the University of North Carolia – Chapel Hill (UNC) that covers novel AAV capsids. The first patent issued in this patent family, U.S. Patent No. 10,532,110, was issued to UNC on January 14, 2020 and has an expected expiration date of November 6, 2036. The second U.S. patent, U.S. Patent No. 10,561,743, was issued to UNC on February 18, 2020 and has an expected expiration date of November 20, 2035. A third U.S. patent, U.S. Patent No. 11,491,242, was issued on November 8, 2022 and has an expected expiration date of January 22, 2037. Abeona owns a second patent family related to certain AAV capsids developed internally at Abeona, and

national stage applications have been filed in the U.S, E.U., and other geographic regions. Any patents issued from those applications would not be expected to expire prior to 2039.

AAV and Ophthalmic Diseases: Abeona has filed a PCT application (PCT/US2021/041527) regarding the multipartite delivery of large transgenes using AAV vectors. The company will file national stage applications in the U.S., E.U., and other geographic regions. Any patents issued from those applications would not be expected to expire prior to 2041. Abeona owns a pending PCT application (PCT/US2022/029797) directed to: 1) novel AAV capsid proteins, and 2) treating ophthalmic diseases via para-retinal administration of AAV vectors. Any patents issued from future PCT applications and national stage applications would not be expected to expire prior to 2042. Abeona owns a pending U.S. provisional application directed to compositions and methods for treating dominant optic atrophy and X-linked retinoschisis.

Financials and Capital Structure

On March 29, 2023, Abeona announced financial results for the fourth quarter and full year 2022. In 2022, the company reported license and other revenues of $1.4 million compared to $3.0 million in 2021. The revenue in 2022 was the result of a clinical milestone achieved in the second quarter of 2022 under a sublicense agreement with Taysha Gene Therapies relating to an AAV-based gene therapy for Rett syndromed. There was also revenue consisting of the recognition of deferred revenue related to grants for the ABO-102 and ABO-101 development programs. Revenue in 2021 resulted from a clinical milestone achieved in December 2021 under a sublicense agreement with Taysha for ABO-202, an AAV gene therapy for CLN1 disease.

Total royalty expense in 2022 was $0.4 million compared to $0 for 2021. The increase was due to royalties owed to the company's licensors resulting from the $1.0 milestone payment due from Taysha. R&D expenses in 2022 were $28.9 million compared to $38.7 million in 2021. The decrease was primarily due to decreased clinical and development work for the MPSIII program due to it being outlicensed/discontinued, decreased stock-based compensation, and decreased salary and related costs. G&A expenses in 2022 were $17.2 million compared to $21.6 million for 2021. The decrease was primarily due to decreased professional fees and decreased stock-based compensation partially offset by increased other costs and increased salary and related costs. Impairment of licensed technology was $1.4 million compared to $0 million in 2021. The licensed technology was for ABO-102 and ABO-101, which the company determined had no future value due to a shift in priorities. Impairment of right-of-use lease assets was $2.5 million in 2022 compared to $0 in 2021. Impairment of construction-in-progress was $1.8 million in 2022 compared to $0 in 2021. The change in the fair value of warrant liabilities was $11.4 million compared to $0 in 2021. The company issued stock warrants that are required to be classified as a liability and valued at fair market value each reporting period. The change in the fair value of warrant liabilities resulted in a gain of $11.4 million primarily due to a reduction in the stock price year over year.

Abeona exited 2022 with cash, cash equivalents, and short-term investments of $52.5 million. We estimate the company has sufficient capital to fund operations into the third quarter of 2024. As of March 21, 2023, Abeona had approximately 17.7 million shares outstanding and, when factoring in stock options, restricted stock, and warrants, a fully diluted share count of 28.2 million.

Risks to Consider

Regulatory Risk: Abeona reported positive results from the Phase 3 VIITAL trial for EB-101 for the treatment of RDEB. EB-101 was successful in treating chronic wounds and reducing pain. The company is expected to file a BLA with the FDA at the end of the second quarter or the beginning of the third quarter of 2023. However, there is no guarantee that the FDA will approve the product or that an approval will occur on the expected timeline. The FDA may require additional data from the company, the FDA may not approve the labeling claims, or there could be a requirement of significant safety warnings on the product's label.

Manufacturing Risk: EB-101 has a complex manufacturing process. The fragility of RDEB skin and the site of biopsy could make initiation of keratinocyte growth and expansion challenging and cause an extension to the usual manufacturing time. In addition, slow cellular proliferation may result in extended manufacturing time. If certain pre-release criteria are not met then the production process could be stopped and a new biopsy would need to be obtained. Since EB-101 is produced under strict manufacturing processes, even minor deviations from the normal process could result in product defects, manufacturing failures, product recalls, or product

liability claims. Any significant disruptions to the company's manufacturing process, including issues with retaining qualified personnel, supply chain issues, or findings by regulatory authorities during routine inspections, may delay or disrupt the commercialization of EB-101.

Commercial Risk: EB-101 has not been approved by the FDA, thus until that authorization occurs the company will not be able to commercialize the product. Even if the FDA approves EB-101, the company may not be able to successfully commercialize the product. The commercial success of EB-101 will depend upon the acceptance of the product by physicians, patients, and healthcare payors. Acceptance of the product will depend on a large number of factors, including the actual and perceived efficacy of EB-101, the convenience of the product and the cost of the product. Other companies are developing RDEB therapies, and those products may be more effective or less costly than EB-101, which could render EB-101 obsolete and noncompetitive.

MANAGEMENT PROFILES

Vishwas Seshadri, PhD – Chief Executive Officer

Dr. Vishwas (Vish) Seshadri, Ph.D., M.B.A., joined Abeona as Head of Research & Clinical Development in June 2021 and was appointed President and Chief Executive Officer, and member of the Company's Board of Directors, in October 2021. Dr. Seshadri has more than 20 years of experience including academia and various senior and executive leadership roles in the life sciences industry overseeing product development, regulatory submissions, and commercialization for novel therapies including personalized, autologous cell and gene therapies. Prior to joining Abeona, Dr. Seshadri served in roles of increasing responsibility at Celgene Corporation, now a subsidiary of Bristol-Myers Squibb Company (BMS), where he focused on development and commercialization of novel therapies in hematology and oncology. Most recently, he led the team responsible for the launch of Breyanzi® (lisocabtagene maraleucel; liso-cel), an autologous CD19-directed chimeric antigen receptor (CAR) T cell therapy for relapsed or refractory large B-cell lymphoma. Previously, he was Head of Early-Stage Upstream Process Development for Biologics at Dr. Reddy's Laboratories. Dr. Seshadri completed his Ph.D. in Microbiology, Immunology & Molecular Biology and his post-doc in epigenetics at University of Arizona, and earned his M.B.A. in Finance and Healthcare from the Wharton School of the University of Pennsylvania.

Dmitriy Grachev, MD, PhD – Chief Medical Officer

Dmitriy Grachev, M.D., Ph.D. has over 20 years of industry experience and a track record that includes multiple global drug approvals while leading clinical development programs at pharmaceutical and biotechnology organizations. Dr. Grachev was appointed as Chief Medical Officer in February 2023 after serving as Abeona's consulting Head of Clinical Development since August 2021. Prior to Abeona, Dr. Grachev served as Vice President, Clinical Development at Marinus Pharmaceuticals, Inc. Prior to that role, he was Chief Medical Officer at Cellectar Biosciences, Inc. Previously, he served as Global Development Leader and Head of Innovative Clinical Trials Initiative, R&D for TEVA Branded Specialty Pharmaceuticals. Dr. Grachev also served in clinical development and medical affairs leadership roles at GE Healthcare, Novartis, GSK plc, Merck, Schering-Plough Corporation, Sanofi-Aventis, and BioClinica. Dr. Grachev earned his M.D. with highest honor in General Medicine from Bogomolets National Medical University, and his Ph.D. in Medical Sciences from the Shupyk National Medical Academy of Postgraduate Education.

Brian Kevany, PhD – Vice President, Chief Technical Officer and Head of Research

Brian Kevany, Ph.D., joined Abeona at the beginning of 2018 as a scientist in the product development department bringing 15+ years of molecular biology and biochemistry research training to Abeona. Prior to joining Abeona, he managed a small biotechnology startup company which utilized next-generation sequencing for high throughput genotyping in both the medical and agricultural spaces. A postdoctoral research position at the University of Wisconsin-Madison, working on developing new first-line antibiotics to treat drug-resistant tuberculosis, and a Fellowship at Case Western Reserve University, studying a wide range of vision research topics, resulted in an exemplary publication record in a wide range of peer-reviewed journals. His research at Case Western, under the mentorship of Dr. Krzysztof Palczewski, involved studying both the biochemical basis of retinal development as well as the pathophysiology of animal models of blinding diseases. Prior to his postdoctoral research, he earned a Ph.D. in Molecular and Cellular Biology from the University of Florida and a B.S. degree with honors from Michigan State University.

Joseph Vazzano – Chief Financial Officer

Joseph (Joe) Vazzano joined Abeona as Chief Financial Officer in March 2022. Before joining Abeona, Mr. Vazzano served as Chief Financial Officer of Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue") from February 2019 to January 2022. Prior to that, he served as Avenue's Vice President of Finance and Corporate Controller since August 2017. During his tenure at Avenue, Mr. Vazzano secured multiple equity financings for Avenue and served in a leadership role for signing a complex, two-stage acquisition of Avenue with future contingent value rights. Previously, Mr. Vazzano served as Assistant Corporate Controller at Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT) from October 2016 to July 2017, where he helped grow the finance and accounting department during the company's transition from a development-stage company to a fully integrated commercial organization. Mr. Vazzano has a Bachelor of Science degree in Accounting from Lehigh University and is a Certified Public Accountant in the State of New Jersey.

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VALUATION

We are initiating coverage of Abeona Therapeutics Inc. with a valuation of $10.00. Abeona is a biopharmaceutical company developing cell and gene therapies for rare genetic diseases. The lead clinical program is EB-101, which is an autologous, gene-corrected cell therapy for the treatment of the ultra-rare orphan disease recessive dystrophic epidermolysis bullosa (RDEB). In November 2022, the company announced positive topline results from the Phase 3 VIITAL™ trial, which showed that EB-101 met its two co-primary efficacy endpoints demonstrating statistically significant, clinically meaningful improvements in wound healing and pain reduction. The treatment was also shown to be safe and well-tolerated as there were no reports of treatment-related serious adverse events. Based on these results, we anticipate the company filing a Biologics License Application (BLA) with the FDA late in the second quarter or early in the third quarter of 2023. Approval of EB-101 may also include a priority review voucher (PRV). PRVs are fully transferrable and have recently been sold for approximately $100 million. Lastly, the company's proprietary capsids and gene constructs (including the AIM™ adeno-associated virus (AAV) capsid library) are being developed for ophthalmic conditions. The novel capsids are designed to have highly selective tissue/cell tropism and reduced immune response, which could offer the potential for re-dosing.

EB-101

EB-101 is an autologous, gene corrected cell therapy that contains a functioning *COL7A1* gene inserted into a patient's keratinocytes (skin cells) using a retrovirus. The purpose of EB-101 is to restore functional collagen VII to patient's own skin cells so that wounds can properly heal and have less chance of recurring in the future. EB-101 is administered using a standard surgical procedure that is akin to a skin graft.

In November 2022, Abeona announced positive topline results for the Phase 3 VIITAL study of EB-101 for the treatment of large chronic RDEB wounds. The study evaluated the safety and efficacy of EB-101 in 43 large chronic wound pairs in 11 subjects with RDEB. The co-primary endpoints of the study were: 1) the proportion of RDEB wound sites with ≥ 50% healing from baseline when comparing treated with matched untreated wound sites at the six-month timepoint, and 2) pain reduction associated with wound dressing change that was assessed through the scores of the Wong-Baker FACES scale by comparing treated and matched untreated wounds at the six-month timepoint.

Results from the VIITAL study showed that 81% of the wounds treated with EB-101 showed ≥ 50% healing at the six-month timepoint compared to only 16% of control wounds (P<0.0001). The mean pain reduction for wounds treated with EB-101 was 3.07 points on the Wong-Baker FACES scale, compared to just 0.90 points for control wounds (P=0.0002). In regards to safety and tolerability, EB-101 was well tolerated and there were no treatment-related serious adverse events (SAEs) and no safety signals observed in the VIITAL study or during the clinical development program.

Valuation

We value Abeona using a probability-adjusted discounted cash flow model that takes into account potential future revenues of EB-101 for the treatment of RDEB in the U.S along with the sale of the PRV. We model for Abeona to commercialize EB-101 in the U.S., with the potential for a commercialization partner for international markets. The ABO-50X programs are not currently included in the valuation as yet since they are still preclinical but represent potential upside to the valuation.

There are approximately 3,850 RDEB individuals estimated to be living in the U.S. We conservatively estimate that approximately half of RDEB patients would have access to treatment and that approximately 80% would choose EB-101 to treat their large chronic wounds. This leads to a target treatment population of approximately 1500. We estimate that the company could charge between $500,000 and $900,000 per treatment (for modeling purposes we use $700,000 per treatment), and that each patient would likely require two treatments to address each of their chronic wounds.

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We model for the BLA to be filed in the third quarter of 2023 and for FDA approval to be granted in early 2024. We estimate for peak sales of $120 million achieved six years after launch. Using an 85% probability of approval and a 12% discount rate leads to a net present value for EB-101 of $92 million. In addition, we anticipate a PRV being issued in connection with the approval of EB-101. We model for the PRV to be sold for $100 million (which is in line with recent sales of PRVs) in 2024 and with an 85% probability of success the net present value for the PRV is $85 million.

Combining the valuation for EB-101, the PRV, the company's current cash position, and potential cash from the exercise of $4.75 warrants leads to a net present value for the company of $265 million. Abeona's current fully diluted share count is approximately 26.4 million (when counting stock options and the warrants with a $4.75 strike price), which leads to a valuation of $10 per share.

PROJECTED FINANCIALS

Abeona Therapeutics Inc.	2022 A	Q1 E	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
EB-101	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$11.0	$44.0
License and other revenues	$1.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$1.4**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$11.0**	**$44.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0	$4.0
Gross Margin	*100%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*91%*	*91%*
Royalties	$0.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & development	$29.0	$8.0	$8.0	$8.0	$8.0	$32.0	$35.0	$37.0
General & administrative	$17.3	$4.0	$4.3	$4.5	$4.7	$17.5	$25.0	$30.0
Depreciation and Amortization	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Impairment of licensed technology	$1.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Impairment of right-of-use lease asset	$2.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Impairment of construction-in-progress	$1.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($50.9)	($12.0)	($12.3)	($12.5)	($12.7)	($49.5)	($49.0)	($23.0)
Operating Margin	*-3600.8%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-445.5%*	*-52.3%*
Non-Operating Expenses (Net)	$11.2	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.5)	($0.5)
Pre-Tax Income	($39.7)	($12.1)	($12.4)	($12.6)	($12.8)	($49.9)	($49.5)	($23.5)
Deemed Dividends Series A and B Preferred Stock	$3.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($43.5)**	**($12.1)**	**($12.4)**	**($12.6)**	**($12.8)**	**($49.9)**	**($49.5)**	**($23.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.53)**	**($0.68)**	**($0.70)**	**($0.63)**	**($0.64)**	**($2.65)**	**($2.15)**	**($0.94)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	7.9	17.7	17.7	20.0	20.0	18.9	23.0	25.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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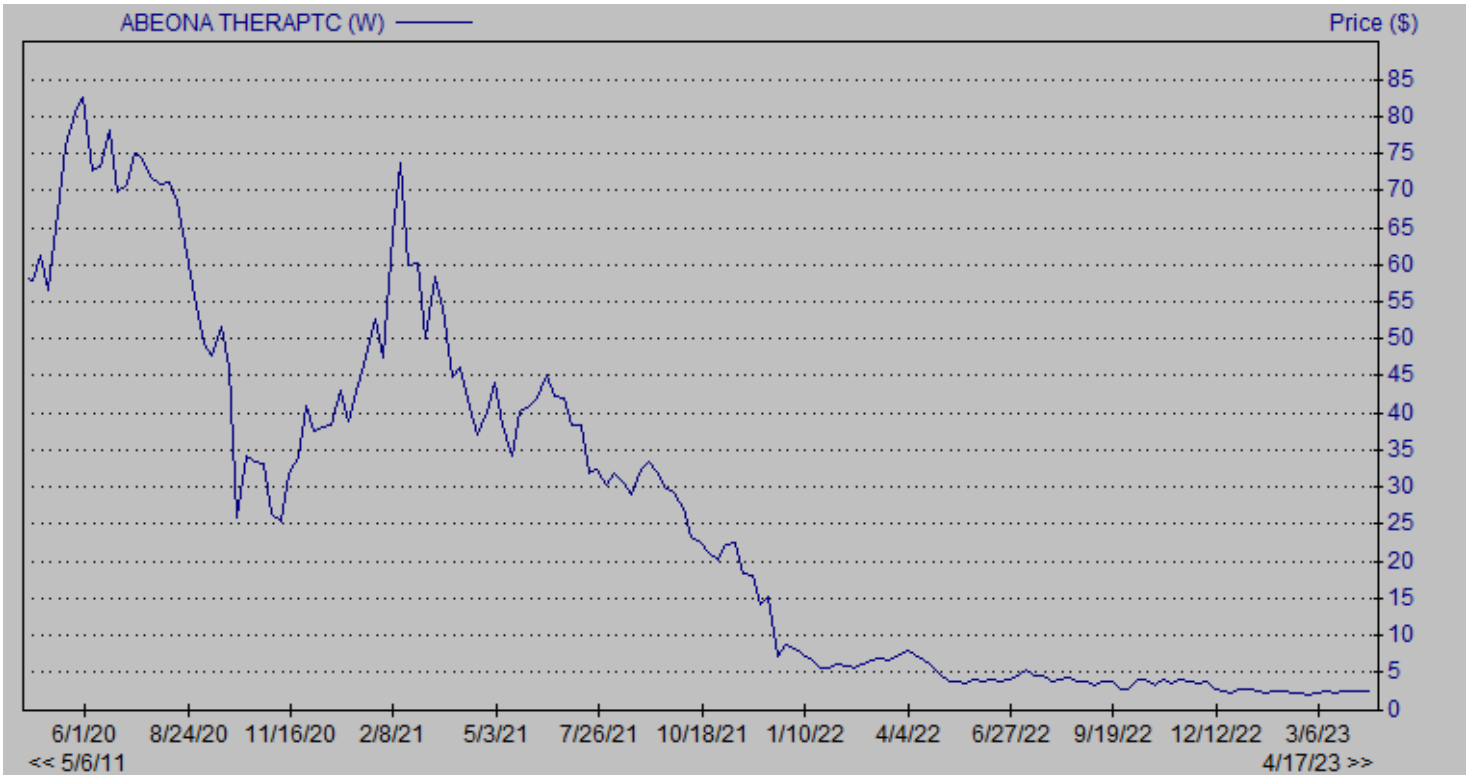
HISTORICAL STOCK PRICE



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