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August 16, 2023
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RVL Pharmaceuticals plc (RVLP: NASDAQ)

RVLP: Second Quarter Results

We apply an 18.0x multiple to 2028 earnings and a 15.0x multiple to 2028 EBITDA, then discount the blended result to present using a 20% factor to generate our target price.

Current Price (8/15/2023)	$0.42
Valuation	**$1.60**

OUTLOOK

RVL Pharmaceuticals commercializes Upneeq® for the treatment of acquired blepharoptosis, or low-lying eyelids. While its primary use is for a medical condition that limits vision, the benefits extend to the aesthetics market where it improves appearance, avoiding a sleepy look.

Following successful pivotal trials measuring superior visual field deficits and upper eyelid elevation, RVL launched Upneeq in late 2020 to eye care professionals. Commercialization efforts later expanded to ophthalmology, optometry and oculoplastic specialties. RVL began pursuing the aesthetics market in early 2022 driving rapid growth off of a small base.

RVL controls its own pharmacy which can either distribute directly or maintain virtual inventory allowing providers to buy product and dispense directly to patients. Future efforts may pursue digital marketing and online pharmacy to improve relationships with customers.

Further growth may come from the Santen agreement for ex-US development of Upneeq, especially in Asia. Several milestones have been paid and upon approval in designated territories royalties will be owed to RVL. Pivotal trials are underway and first sales may take place in 2025.

SUMMARY DATA

52-Week High	**$2.99**
52-Week Low	**$0.36**
One-Year Return (%)	**-80.0**
Beta	**1.0**
Average Daily Volume (sh)	**90,919**
Shares Outstanding (mil)	**99.5**
Market Capitalization ($mil)	**41.8**
Short Interest Ratio (days)	**0.6**
Institutional Ownership (%)	**49.1**
Insider Ownership (%)	**27.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(In millions of USD)

	Q1 (Mar)	**Q2** (Jun)	**Q3** (Sep)	**Q4** (Dec)	**Year** (Dec)
2022	$21.4 A	$8.4 A	$10.0 A	$9.8 A	$34.2 A
2023	$8.8 A	$8.3 A	$7.9 E	$10.6 E	$35.5 E
2024					$52.6 E
2025					$76.3 E

Earnings per Share

	Q1 (Mar)	**Q2** (Jun)	**Q3** (Sep)	**Q4** (Dec)	**Year** (Dec)
2022	-$0.08 A	-$0.14 A	-$0.16 A	-$0.18 A	-$0.58 A
2023	-$0.12 A	-$0.24 A	-$0.11 E	-$0.11 E	-$0.57 E
2024					-$0.42 E
2025					-$0.26 E

WHAT'S NEW

2Q:23 Financial and Operational Results

RVL Pharmaceuticals, plc (NASDAQ: RVLP) reported 2Q:23 results in a press release and conference call before market open on August 14, 2023. The company subsequently filed its Form 10-Q with the SEC. RVL reported product revenues of $8.3 million, a 2% decrease relative to product sales generated in the prior year quarter. No license revenues were recognized. Highlights since the first quarter update in May include a proposal to waive offer obligations related to minority shareholder rights and a business update which indicated RVL management was seeking a strategic transaction. The e-commerce portal, Elevate, was launched in early July and is up and running and will allow increased interaction with patients while maintaining the connection with providers and aesthetic practices. Further data and analytics from this platform are expected to help improve the loyalty and efficiency of Upneeq users.

In the second quarter, RVL reported revenues of $8.3 million, which declined both sequentially and compared with the prior year. A reduction in sales expenditures and sales force reduced the support behind acquisition of new accounts. RVL has recognized that increased awareness is critical to success of Upneeq and will expand its direct-to-consumer advertising employing a variety of marketing tools including social media.

The sales force has sold to 5,400 locations, up 600 from the prior quarter with 2,100 locations reordering. The number of pharmacy prescribers also increased to 21,000 up by about 1,000. Gross and operating margins improved and operating expenditures were down over prior quarter amounts and compared with averages for 2022. This ignores the $13.9 million write down related to arbaclofen, which was classified as abandoned. The changes in the topline and expense structure reflect management's focus on profitable growth and customer loyalty rather than on new accounts. Despite the improvement in quarterly net loss, the decline in the revenue trend has motivated the RVL team to align itself towards increased marketing efforts that will serve to increase awareness and resume the growth trend in the topline.

2023 year to date milestones:

- Telemedicine channel opened – 3Q:22
- Launch of e-commerce platform – 1Q:23
- Special Protocol Assessment reached with FDA for arbaclofen – May 2023
- Rollout of Elevate – July 2023

Revenues of $8.3 million were reported for 2Q:23. Gross margins improved to 76% and, ignoring the arbaclofen write down, operating expense was $14.4 million yielding a net loss of ($10.0) million or ($0.10) per share.

For the quarter ending June 30, 2023 and versus the same three-month period ending June 30, 2022:

- Revenues of $8.3 million were down 2% vs. $8.4 million due to a decrease in sales volume partially offset by a price increase;
- Product gross margin was 76% compared to a 74% rate. Lower royalty expense and lower sales volumes contributed to the decrease in cost and increase in margin;
- Selling, general & administrative expense fell 31% to $13.9 million from $20.2 million impacted by lower compensation and training costs, decreased legal, insurance, rent and other professional fees, a decline in share-based compensation and a contraction in Upneeq marketing expenses;
- Research & development expense totaled $547,000, falling 53% from $1.2 million. A reduction in spend for arbaclofen, RVL-1201 (Upneeq) and other R&D dramatically reduced expenses in this category;
- Arbaclofen was impaired to the tune of $13.9 million on discontinuation of the program;
- Other non-operating income represented another ($2.0) million of expense related to fair value losses;
- Net loss, including the arbaclofen write-down, was ($23.9) million vs. ($12.1) million or ($0.24) and ($0.14) per share, respectively.

As of June 30, 2023, cash and equivalents stood at $19.2 million. This amount compares to a $44.5 million balance in cash and equivalents held at the end of 2022. Cash burn for 2Q:23 was ($13.0) million. Based on the cash burn rate to date and the cash balance, RVL will require a capital infusion in the near term.

Strategic Alternatives
In a July 5th business update, RVL announced that it will consider strategic alternatives, including the pursuit of complementary aesthetics products with revenue and synergies with Upneeq. In the second quarter press release, the company noted that it is in discussions with strategic targets that may accelerate Upneeq sales, broaden the company's portfolio and drive growth. Further details were not available to evaluate the strategic opportunity; however, we are strong believers in leveraging an in-place sales structure that can layer on additional products at minimal additional cost. RVL offers a telemedicine channel, its Elevate e-commerce platform and a sales force in place that is making daily calls on practices. A new, related product could easily be added to the portfolio of products and generate strong incremental margins. While we do not know the identity of the products being considered or the extent of their complementarity with Upneeq, it appears that RVL is in the later stages of its negotiations and we may hear additional details soon.

Board Changes and Strategy
In a recent Form 8-K filing, RVL announced that two directors had resigned from the board. As we understand it, some members of the board recognized the difficult fundraising environment that small capitalization life sciences companies are facing and favored minimizing cash burn. However, this had the unintended effect of negatively impacting sales and led to changes in the board composition and its strategy to get the topline back on track. It appears that the remaining board members are now aligned in their desire to invest in topline growth despite the hazards of difficult capital markets. In the 2Q:23 press release, management notes that it is now seeking to drive consumer awareness in order to unlock growth for Upneeq. Incremental sales will be heavily oriented towards the consumer and encourage the use of the subscription model.

Athyrium Amendment
RVL has been able to renegotiate its financing agreement with Athyrium, which management believes provides additional flexibility. Athyrium's support may allow the company to sidestep many of the risks of increasing cash burn and take the long view as the company pivots toward increasing investment in product awareness and new sales growth.

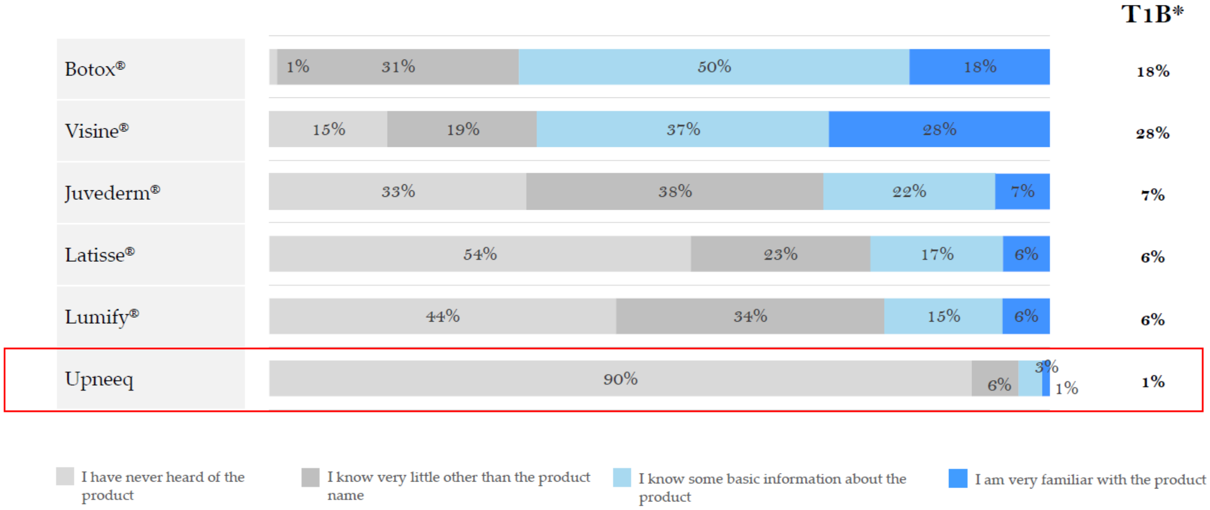
Contributors to Revenue Decline
Over the prior year, as part of the effort to reduce costs, the sales team was reduced from 75 to 45 today. While reorders have been strong, with 2,100 locations going a second round, new sales have not been keeping up due to the reduction in sales force. Based on company commentary, we anticipate that marketing spend will accelerate in the second half and sales will resume their upward trajectory with a lag.

Moving Down the Income Statement
As we look at the income statement, we observe the year over year decline in sales but also the increase in gross profit to $6.3 million from $6.2 million in the prior year. Better gross margin of 76% (compared to 74% in 2Q:22) was achieved on account of stronger Upneeq pricing and lower royalty expense. Selling, general and administrative expenses were down 31% to $13.9 million and research and development fell 53% to $547,000. This produced an operating loss of ($8.1) million compared to ($15.1) million in the prior year. Second quarter 2023 results show that RVL was able to dramatically improve the efficiency of its operations with cost cutting; however, it was at the expense of growth.

We believe that investment needs to be made to penetrate the market and drive brand awareness. Close attention should be paid to the efficiency of sales dollars to ensure that a dollar spent on sales is generating more than it costs.

Turnaround Strategy
RVL has outlined its strategy to inflect growth in the second half of 2023 with efforts to improve consumer awareness, develop the provider base and grow the field force to support conversion at the practices. Below we show a graphic from RVL's latest presentation that illustrates the awareness of many of the leading products in the aesthetics market. Note that the T1B refers to the proportion of those surveyed who are very familiar with the product.

Exhibit I – Relative Consumer Awareness of Aesthetics Products[1]



Waiver Proposal of Takeover Rules

In mid-June, RVL announced results of a vote that would allow the company to waive the requirements of Rule 9 of the Irish Takeover Rules.[2] Rule 9 requires an entity that acquires a 30% or more interest in the voting rights of a target company to make a mandatory offer for all of its remaining shares. The requirement ensures that all share-holders have an equal opportunity to participate in the takeover and to receive a fair price. The purpose of Rule 9 is to ensure that takeovers are fair and equitable and that minority shareholders are protected from the competing in-terests of controlling shareholders.

Independent shareholders approved the waiver which will allow RVL's major shareholders and management team to acquire a number of shares above the previous threshold. Major shareholders will now be able to increase their shareholding as shown in the exhibit below without incurring an obligation under Rule 9 to make a general offer to other shareholders.

Exhibit II – Updated Thresholds for Significant Shareholders[3]

	March 31, 2023 Shareholding (Number)	March 31, 2023 Shareholding (%)	Potential Shareholding Following Share Issues (%)
Avista Healthcare Partners, L.P.	23,730,864 ordinary shares	23.89%	29.56%
Altchem Limited and Orbit Co-Invest A-1 LLC	23,667,540 ordinary shares	23.82%	29.50%
Management Individuals (as defined in the Proxy Statement)	3,086,261 ordinary shares	3.11%	4.07%

Business Update

RVL provided a business update on July 5th announcing that it had been in discussions to consider strategic alter-natives including the acquisition of a counterparty in an all stock transaction. The company is also lining up financ-ing sources to fund the combined company if the transaction is completed. Based on the press release we believe this may be a complementary product to Upneeq that will leverage the existing sales force with minimal additional cost and strong potential synergies.

[1] RVL Pharma corporate Presentation, August 2023.
[2] See page 77 of document.
[3] RVL Pharma press release dated June 15, 2023.

<u>Best Eye Drop for Drooping Lids Award by NewBeauty</u>

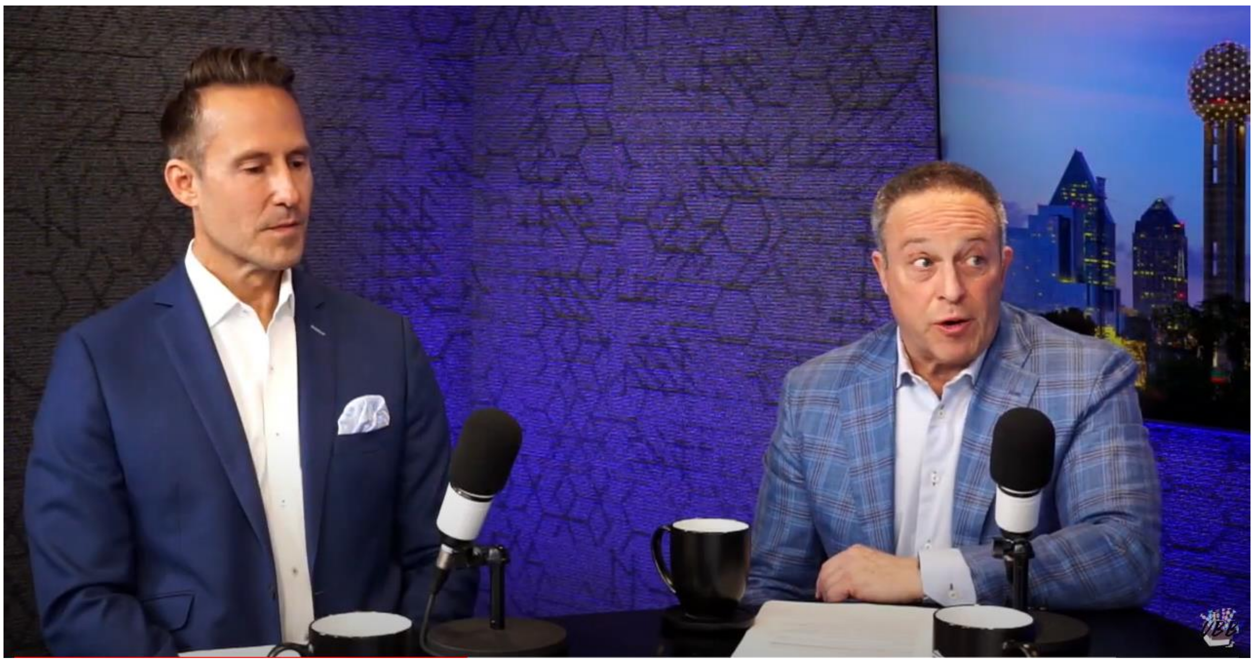
RVL Pharmaceuticals' Upneeq® was selected as the winner in the professional treatment category as "Best Eye Drop for Drooping Lids" in the NewBeauty 13th Annual Beauty Awards announced in April. Upneeq was competing along with more than 10,000 other products for awards and was one of 399 that were selected in a variety of categories. Criteria for the award required the product to solve an aesthetic concern and meet NewBeauty's testing standards.

Members of the independent panel that selected Upneeq were gathered from an esteemed group of opinion leaders, medical and industry professionals and advisors. One of the physician judges noted that Upneeq works in both ptotic eyes in about five minutes, providing a one-to-two-millimeter lift. The award will be included as a segment in the April 4, 2023 issue of NewBeauty. We expect this award will increase awareness of Upneeq and favorably affect product perception.

Management Interviews with CEO Brian Markison and VP of Sales Aaron Green

In late April, RVL's CEO, Brian Markison and VP of Sales Aaron Green participated in a series of interviews which discussed the company's commercialization strategy for Upneeq, recent confirmatory research published in the Journal of Plastic, Reconstructive and Aesthetic Surgery, Upneeq's mechanism of action and trends in the aesthetics industry among other topics. See below for links to the interviews:

Exhibit III – Interviews with Brian Markison (R) and Aaron Green (L)[4]



- UPNEEQ: RVL Pharmaceuticals' Compelling Product
- RVL Pharmaceuticals' Aesthetics Strategy
- Further Support for RVL Pharmaceuticals' UPNEEQ
- RVLP: How Does UPNEEQ Work and What is Ptosis?
- RVL Pharmaceuticals' UPNEEQ Riding the Multi-Billion Dollar Wave in Aesthetics
- RVL Pharmaceuticals' UPNEEQ: A Complement to the Aesthetics Market
- A Conversation with RVL Pharmaceuticals: What's Happening in the Industry?

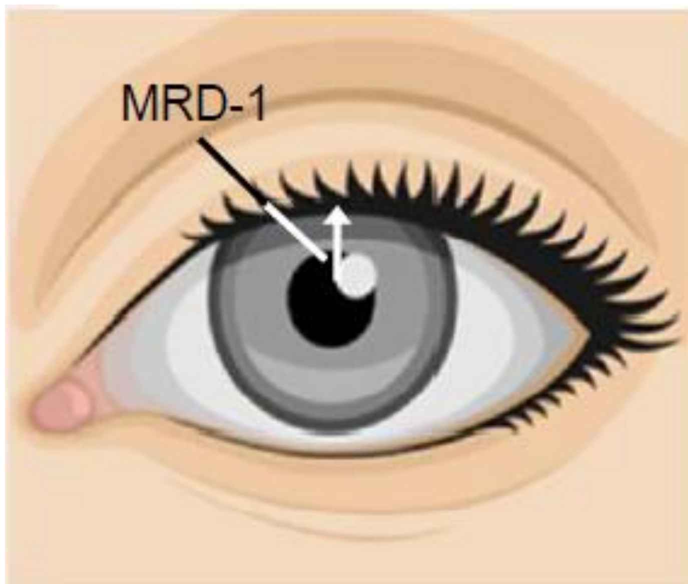
[4] Source: Screen shot from video interview.

Upneeq Updated Study

The Journal of Plastic, Reconstructive and Aesthetic Surgery published an article entitled The Effect of Topical Oxymetazoline on Eyelid Position, Eye Redness, and Patient-Reported Eye Appearance: A Randomized Controlled Trial.[5] The study, as apparent from its title, examined the effect of oxymetazoline 0.1% on eye features important for eye aesthetics. We had an opportunity to speak with one of the study authors, Dr. Wendy W. Lee, who is at the Department of Ophthalmology at the University of Miami. She highlighted the study's findings in context of both functional and aesthetic benefit.

RVL Pharmaceuticals is commercializing the product evaluated in the article, branded Upneeq. Other studies have been previously conducted which were required for FDA approval. Endpoints for these studies included change in baseline visual field and measurement of marginal reflex distance (MRD). The journal study referenced above added some new elements including perception of eye redness and patient perception of eye appearance to the marginal reflex distance metric.

Exhibit IV – Marginal Reflex Distance (MRD)[6]



The trial evaluated 114 patients, evenly split between treated patients and controls. It was conducted from April 2021 to April 2022 at the University of Miami. The double-blind study enrolled patients 18 and above with stable eye health other than minor ptosis.

Mechanism of Action
Oxymetazoline hydrochloride 0.1% works as a direct-acting α-adrenergic receptor agonist. Müller's muscle, which elevates the upper eyelid, presents α-2 adrenergic receptors that contract in response to sympathetic stimulation or topical adrenergic agonists. The α-2 effects extend to ocular surface vasoconstriction, which decreases eye redness.

Findings
The primary outcome measure used in the article was the change in marginal reflex distance (MRD) of the upper and lower eyelid. Secondary outcomes were the change in eye redness as measured through the Validated Bulbar Scale (VBS) and patient-perceived eye appearance. During our conversation, study author Dr. Lee noted that oxymetazoline 0.1% has both a functional and aesthetic benefit, not only for widening the eye but it also for making it appear whiter. In an extension from previous studies, this work examined eye whiteness and quality of life metrics for patients. The formulation is a good alternative to surgery and can even help patients that are appropriate for surgery, providing temporary relief and a bridge as they are waiting for surgery. Safety is favorable and there are no concerns over long term use as the underlying API has been evaluated and used for many years in other applications.

[5] Shoji, M.K. *et al*. The effects of topical oxymetazoline on eyelid position, eye redness, and patient-reported eye appearance: A randomized controlled trial. Journal of Plastic, Reconstructive and Aesthetic Surgery. May 2023.
[6] RVL Pharma corporate Presentation, August 2022.

Two hours after application of oxymetazoline hydrochloride 0.1%, the mean MRD of the upper eyelid was 5.1 mm in the treatment group and 4.1 mm in the control group. The oxymetazoline group generated an increase in MRD1 by 0.9 mm (+/- 0.9) while the control group produced a decrease of 0.3 mm (+/- 0.4). A statistically significant change was measured in the difference between the two groups MRD with a p-value below 0.001. The change in *lower* eyelid MRD was not statistically significant. Average change eye redness measured by the VBS was -2.6 in the treatment group and -0.5 in the control group, with a p-value of 0.002. 113 of the 114 enrolled patients completed the eye appearance questionnaire using the FACE-Q eye appearance scale.[7] The pre- and post-treatment FACE-Q appearance score improved by 3.1 units for the oxymetazoline group and by 0.8 for the control group. Results were statistically significant with a p-value of 0.0002.

Exhibit V – Change of Eyelid Position and Eye Redness After Drop Instillation[8]

	Oxymetazoline group (n = 57)	Control group (n = 57)	p-value
Change in MRD1 (mm)	0.9 +/-0.9	-0.3 +/-0.4	p<0.001
Change in MRD2 (mm)	0.2 +/-0.7	-0.1 +/-0.8	p=0.07
Change in PF* (mm)	1.1 +/-1.1	-0.4 +/-0.8	p<0.001
Change in Eye Redness	-2.6 +/-4.4	-0.5 +/-2.3	p=0.002

*PF – Palpebral fissure, the opening between the upper and lower eyelids.

92 patients completed a survey evaluating their eye appearance. The proportion of participants that identified an improvement in eye appearance, eye size and eye redness was substantially greater in the oxymetazoline group. We summarize the patient-reported results below.

Exhibit VI – Comparison of Patient-Reported Eye Appearance Before & After Drop Instillation[9]

	Oxymetazoline group (n = 44)	Control group (n = 48)	p-value
Patient-reported change in eye appearance			
Improved	29 (65.9%)	14 (29.1%)	p = 0.002
Same	14 (31.8%)	33 (68.8%)	
Worse	1 (2.3%)	1 (2.1%)	
Patient-reported change in eye size			
Larger	29 (65.9%)	13 (27.1%)	p = 0.008
Same	14 (31.8%)	31 (64.6%)	
Smaller	1 (2.3%)	4 (8.2%)	
Patient-reported change in eye redness			
Less red/more white	26 (59.1%)	13 (27.1%)	p = 0.003
Same	18 (40.9%)	32 (66.7%)	
More red/less white	0 (0%)	3 (6.3%)	

Safety was very good with nine (14.0%) treatment emergent adverse events (TEAEs) reported by seven oxymetazoline participants. This compares to 5 (8.7%) TEAEs reported in the control group. All TEAEs were mild and included headache, dry eye, blurry vision that self-resolved in 10 minutes and dizziness.

[7] The FACE-Q Eye Appearance Module is a patient-reported outcome measure used to evaluate the appearance of the eyes and surrounding areas. It is a comprehensive, validated questionnaire designed to assess patients' perceptions of their facial appearance and the impact on their quality of life. The module consists of a set of questions that ask patients to rate the appearance of their eyes and surrounding areas, such as the eyelids, eyebrows and under-eye area. The questions are designed to evaluate factors such as the presence of wrinkles, bags or puffiness, skin tone and overall eye appearance. The responses are used to generate a score that reflects the patient's satisfaction with their eye appearance. The FACE-Q Eye Appearance Scale is used by healthcare providers and researchers to evaluate the outcomes of eye-related treatments, such as eyelid surgery, eye lifts, or treatments for under-eye bags. It can also be used to assess the impact of eye appearance on patients' quality of life and self-esteem.
[8] Zacks analyst work summarized from article.
[9] Zacks analyst work summarized from article.

Exhibit VII – Examples of Upneeq Impact[10]

Summary

RVL Pharmaceuticals reported a difficult quarter with revenues down both sequentially and year over year. We did not expect such a turn in our estimates; however, we recognize that the reduction in spending on commercialization and a material reduction in the sales force had a dramatic effect on topline with a lag. RVL has recognized that it must make further investments in sales and now has a board of directors that appears to be aligned on the strategy to increase awareness of the product and leverage its telemedicine, e-commerce and salesforce platforms to reinvigorate revenues. Indications that a complementary product is near at hand signal a new offering that may provide leverage to reduce cash burn and allow the investments required for the aggressive double-digit growth to return.

We adjust our estimates to reflect the anticipated trajectory of revenues, margins and expenses and update our valuation. The model applies an 18x multiple to 2028 EPS of $0.28 and a 15x multiple to 2028 EBITDA of $40 million while adjusting for net debt, then discounts the blended result to present at a 20% rate. This produces our updated valuation of $1.60 per share.

[10] Source: RVL Pharma Corporate Presentation, November 2022. Note that these results are from a prior study and are intended to illustrate the impact. Images from the study cited herein can be found at the link here.

PROJECTED FINANCIALS

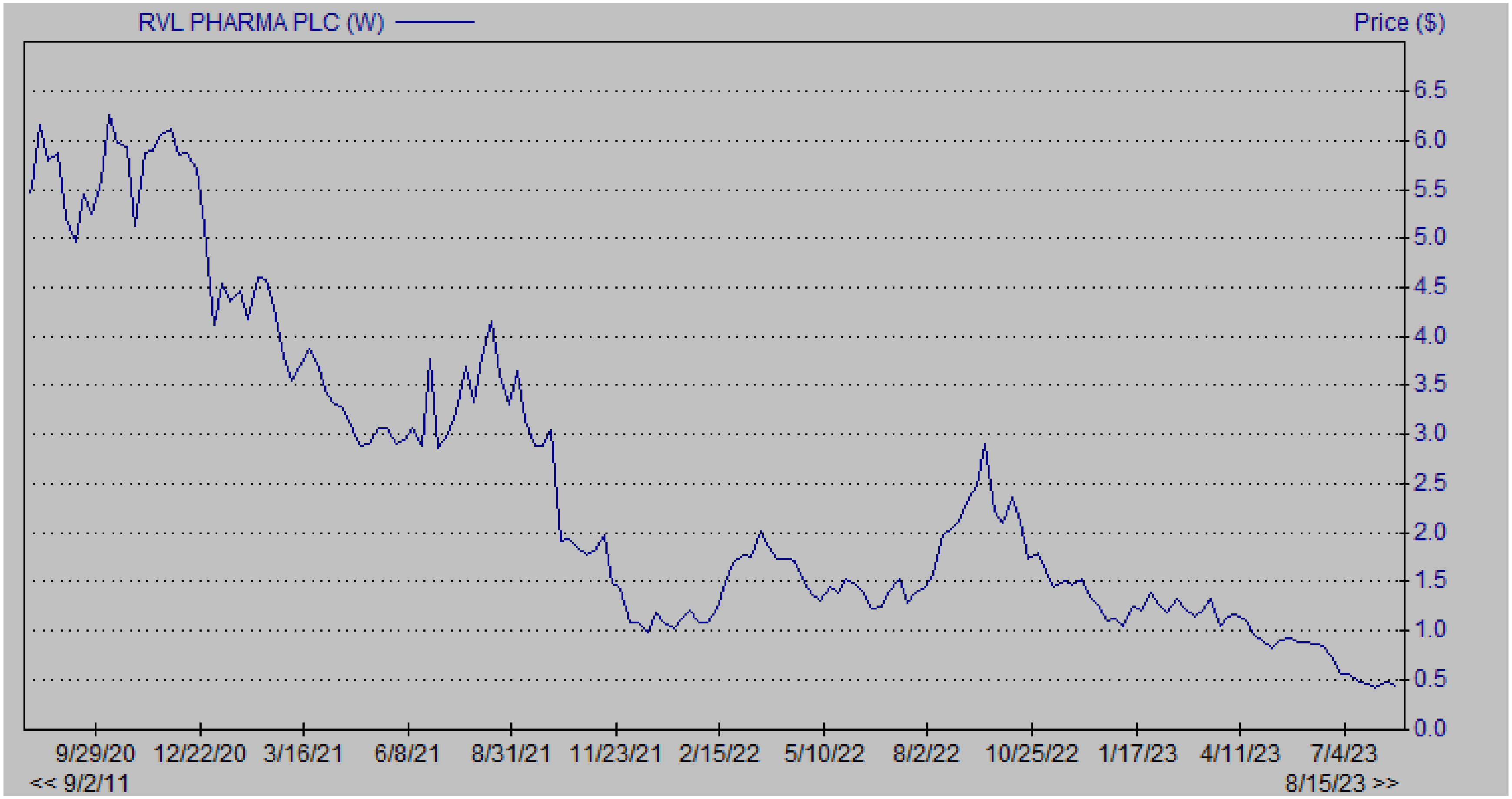
RVL Pharmaceuticals plc. - Income Statement

RVL Pharmaceuticals plc	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US)	**$49,721**	**$8,832**	**$8,258**	**$7,885**	**$10,580**	**$35,555**	**$52,621**	**$76,301**
YOY Growth	*184%*	*-59%*	*-2%*	*-21%*	*8%*	*-28%*	*48%*	*45%*
Cost of Goods Sold	$9,456	$2,299	$1,946	$2,208	$2,962	$9,415	$14,997	$21,364
Gross Margin-Product Sales Only	72%	74%	76%	72%	72%	74%	72%	72%
Gross Profit	$40,265	$6,533	$6,312	$5,677	$7,618	$26,140	$37,624	$54,937
Selling, General & Administrative	$81,979	$16,198	$13,886	$14,000	$16,266	$60,350	$69,400	$71,482
Research and Development	$3,966	$626	$547	$600	$600	$2,373	$2,000	$2,000
Other Expenses	$13,310	$0	$13,900	$0	$0	$13,900	$0	$0
Income from operations	($58,990)	($10,291)	($22,021)	($8,923)	($9,248)	($50,483)	($33,776)	($18,545)
Net Interest Expense	$3,110	$26	$13	$2,200	$2,200	$4,439	$8,800	$8,800
Other Loss (Income)	($10,388)	$1,237	$1,968	$0	$0	$3,205	$0	$0
Pre-Tax Income	($51,712)	($11,554)	($24,002)	($11,123)	($11,448)	($58,127)	($42,576)	($27,345)
Provision for Income Tax	($20)	$58	($113)	$0	$0	($55)	$0	$0
Tax Rate	*0.0%*	*-0.5%*	*0.5%*	*0.0%*	*0.0%*	*0.1%*	*0.0%*	*0.0%*
Net Income	**($51,692)**	**($11,612)**	**($23,889)**	**($11,123)**	**($11,448)**	**($58,072)**	**($42,576)**	**($27,345)**
Reported EPS	**($0.58)**	**($0.12)**	**($0.24)**	**($0.11)**	**($0.11)**	**($0.57)**	**($0.42)**	**($0.26)**
Basic Shares Outstanding	89,797	99,321	99,370	100,816	104,492	101,000	102,000	104,500

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

HISTORICAL STOCK PRICE

RVL Pharmaceuticals plc. – Share Price Chart[11]



[11] Source: Zacks Research System

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