Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive
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RVL Pharmaceuticals plc (RVLP: NASDAQ)

RVLP: First Quarter Results

We apply an 18.0x multiple to 2027 earnings and a 15.0x multiple to 2027 EBITDA, then discount the blended result to present using a 20% factor to generate our target price.

Current Price (5/11/2023)	$0.87
Valuation	**$3.00**

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	**$0.72**
One-Year Return (%)	**-38.3**
Beta	**1.2**
Average Daily Volume (sh)	**70,556**
Shares Outstanding (mil)	**99.3**
Market Capitalization ($mil)	**86.4**
Short Interest Ratio (days)	**1.3**
Institutional Ownership (%)	**49.3**
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	$9.8 E	$13.6 E	$16.7 E	$48.9 E
2024					$71.0 E
2025					$95.8 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	-$0.13 E	-$0.10 E	-$0.08 E	-$0.43 E
2024					-$0.30 E
2025					-$0.14 E

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WHAT'S NEW

1Q:23 Financial and Operational Results

RVL Pharmaceuticals, plc (NASDAQ: RVLP) reported 1Q:23 results in a press release and conference call before market open on May 11, 2023. The company subsequently filed its Form 10-Q with the SEC. RVL reported product revenues of $8.8 million, a 49% increase over product sales generated in the prior year quarter. No license revenues were recognized. Highlights since the fourth quarter update in late March include an award from the New-Beauty aesthetics industry publication and management participation in a series of interviews extolling the virtues of Upneeq. The e-commerce portal, Elevate, is expected to be up and running this summer 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 first quarter, RVL reported revenues of $8.8 million, which is up over prior year levels but down sequentially. 54% of the activity in the quarter were reorders and 4,800 unique medical aesthetic practices had placed orders for Upneeq by quarter end compared to 4,300 at year end 2022. The number of pharmacy prescribers also increased to 19,900 up from 18,400 in the fourth quarter. There were also 500 new medical aesthetic purchasing locations added in the quarter bringing the total to 4,300. Gross and operating margins improved and operating expenditures were down over prior quarter amounts and compared with averages for 2022. The changes in the topline and expense structure reflect management's focus on profitable growth and customer loyalty rather than on new accounts with less durability.

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 $8.8 million were reported for 1Q:23. Gross margins improved to 74% and operating expense was $16.8 million yielding a net loss of ($11.6) million or ($0.12) per share.

For the quarter ending March 31, 2023 and versus the same three-month period ending March 31, 2022:

- Revenues of $8.8 million were down 59% vs. $21.4 million. Prior year amounts include $15.5 million in licensing revenues from Santen. Product revenues increased 49% driven by growth in eye care and reorders;
- Product gross margin was 74% compared to a 64% rate. Gross margin improved on lower royalty expense and leverage from depreciation and cost of goods sold;
- General & administrative expense fell 32% to $16.2 million from $23.8 million impacted by lower compensation and training costs, decreased legal, insurance and other professional fees, a decline in share-based compensation and a contraction in Upneeq marketing expenses;
- Research & development expense totaled $626,000, falling 27% from $862,000. A small increase in Arbaclofen ER spending and a rise in Upneeq spending were more than offset by a decline in other research and development expenses largely related to share-based compensation;
- Other non-operating income netted $1.3 million as a $7.3 million change in fair value of debt and interest expense was offset by a decline in fair value of warrants and a ($5.4) million other non-operating income related to receipt of milestone payments from Alora;
- Net loss was ($11.6) million vs. ($6.8) million or ($0.12) and ($0.08) per share, respectively.

As of March 31, 2023, cash and equivalents stood at $32.6 million. This amount compares to a $44.5 million balance in cash and equivalents held at the end of 2022. Cash burn for 1Q:23 was ($7.0) million compounded by a ($4.9) million draw from financing predominantly related to debt repayments. During the quarter, RVL received cash of $5.0 million from Alora related to a contingent milestone payment. The proceeds were used to repay part of outstanding debt owed to Athyrium.

Best Eye Drop for Drooping Lids Award by NewBeauty

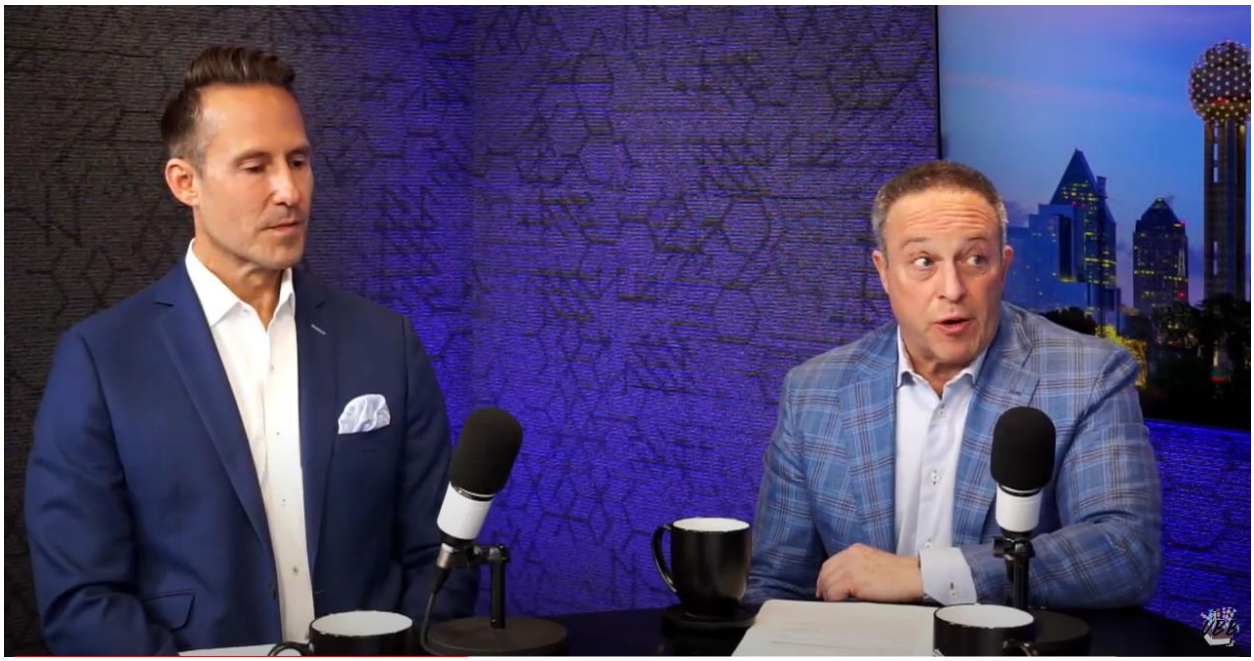
RVL Pharmaceuticals, plc's (NASDAQ: RVLP) Upneeq® was selected as the winner in the professional treatment category as "Best Eye Drop for Drooping Lids" in the NewBeauty 13th Annual Beauty Awards. Upneeq was competing along with more than 10,000 other products for awards and was one of 399 that were 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

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 I – Interviews with Brian Markison (R) and Aaron Green (L)[1]



- 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?

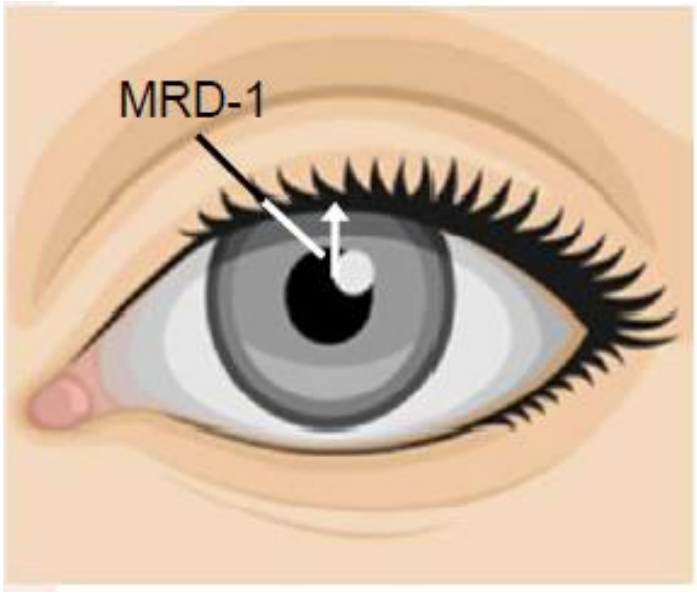
[1] Source: Screen shot from video interview.

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. 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 II – Marginal Reflex Distance (MRD)[2]



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.

[2] 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.[3] 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 III – Change of Eyelid Position and Eye Redness After Drop Instillation[4]

	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 IV – Comparison of Patient-Reported Eye Appearance Before & After Drop Instillation[5]

	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.

[3] 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.

[4] Zacks analyst work summarized from article.

[5] Zacks analyst work summarized from article.

Exhibit V – Examples of Upneeq Impact[6]



Summary

RVL reports first quarter results with revenues increasing over the prior year, but falling sequentially. Gross margins and cost structure improve as the company shifts its focus to improving loyalty and growing existing accounts. In the marketing sphere, RVL moves into the spotlight with its NewBeauty award and top executives participating in an interview highlighting the company's prospects. A recent journal article confirms the benefits of Upneeq, demonstrating oxymetazoline's ability to increase the openness of the eye by raising the upper eyelid. The study endpoints also examined the product's ability to whiten the eye and to produce improved aesthetic appearance. Oxymetazoline 0.1% is an attractive alternative to surgery for minor ptosis and has shown that it can improve patient eye appearance for both eyelid position and redness. Patients can detect the difference as evidenced by responses given in the FACE-Q survey as discussed in the article.

Despite a slowdown in topline, we see management's more cost-effective approach of increasing existing customer loyalty as beneficial to operating margins. An expected upcoming launch of the e-commerce platform, Elevate, is expected to streamline ordering and logistics while improving customer reorders. Favorable treatment in the beauty press, management interaction with the investing public and confirmatory research is expected to provide additional support for the company's future sales growth efforts. We maintain our valuation of $3.00 per share.

[6] 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

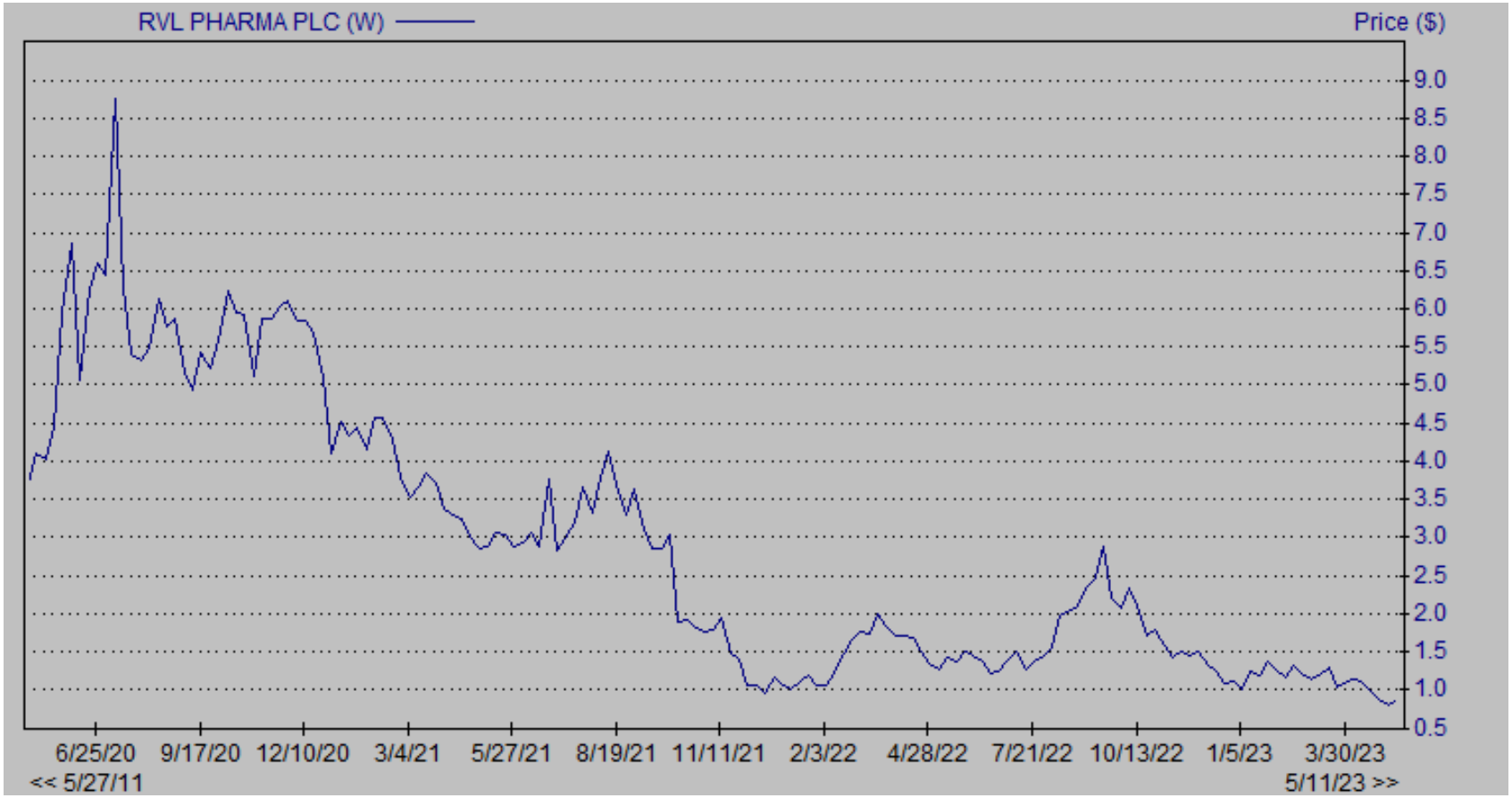
RVL Pharmaceuticals plc	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US)	**$49,721**	**$8,832**	**$9,810**	**$13,552**	**$16,740**	**$48,934**	**$70,954**	**$95,788**
YOY Growth	*184%*	*-59%*	*16%*	*35%*	*71%*	*-2%*	*45%*	*35%*
Cost of Goods Sold	$9,456	$2,299	$2,747	$3,795	$4,687	$13,528	$20,222	$27,779
Gross Margin-Product Sales Only	72%	74%	72%	72%	72%	72%	72%	71%
Gross Profit	$40,265	$6,533	$7,063	$9,757	$12,053	$35,406	$50,732	$68,010
Selling, General & Administrative	$81,979	$16,198	$17,500	$17,240	$17,266	$68,204	$70,250	$72,358
Research and Development	$3,966	$626	$600	$600	$600	$2,426	$2,000	$2,000
Other Expenses	$13,310	$0	$0	$0	$0	$0	$0	$0
Income from operations	($58,990)	($10,291)	($11,037)	($8,083)	($5,813)	($35,224)	($21,518)	($6,348)
Net Interest Expense	$3,110	$26	$2,200	$2,200	$2,200	$6,626	$8,800	$8,800
Other Income	($10,388)	$1,237	$0	$0	$0	$1,237	$0	$0
Pre-Tax Income	($51,712)	($11,554)	($13,237)	($10,283)	($8,013)	($43,087)	($30,318)	($15,148)
Provision for Income Tax	($20)	$58	$0	$0	$0	$58	$0	$0
Tax Rate	*0.0%*	*-0.5%*	*0.0%*	*0.0%*	*0.0%*	*-0.1%*	*0.0%*	*0.0%*
Net Income	**($51,692)**	**($11,612)**	**($13,237)**	**($10,283)**	**($8,013)**	**($43,145)**	**($30,318)**	**($15,148)**
Reported EPS	**($0.58)**	**($0.12)**	**($0.13)**	**($0.10)**	**($0.08)**	**($0.43)**	**($0.30)**	**($0.14)**
Basic Shares Outstanding	89,797	99,321	100,225	100,816	103,638	101,000	102,000	104,500

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

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HISTORICAL STOCK PRICE

RVL Pharmaceuticals plc. – Share Price Chart[7]



[7] Source: Zacks Research System

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